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Information about application	
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Descriptive information

Project title (Swedish)

Effekter av zoledronsyra efter fragilitetsfraktur

Project title (English)

Effects of Zoledronic Acid After a Fragility Fracture: The Fragility Fracture Trial

Abstract and popular scientific description

Please note that the abstract may be used when distributing the application to the reviewers that will make the scientific assessment of it.

Abstract (English)

Background: Each year, fractures affect 95,000 older adults in Sweden. Less than 10% of these adults receive bone-strengthening treatment to prevent new fractures. This low prescription rate is probably influenced by the fact that few clinical trials have examined whether bone-strengthening treatment is effective after a fracture, and no trial has examined whether treatment is effective after a fracture not of the hip or vertebrae, which constitute the majority of fractures.

Purpose and aim: This study will investigate whether zoledronic acid, a widely used bone-strengthening agent, is more effective than placebo in reducing fractures among older adults who have previously suffered a non-hip, non-vertebral fragility fracture.

Methods: We will recruit 2,900 men and women, 65 years of age or older, with a recent non-hip, non-vertebral fragility fracture to a multicenter, randomized controlled trial across Sweden. Each participant will be randomized to receive 2 intravenous infusions of zoledronic acid (5 mg) or placebo, given at baseline and at 2 years. Participants will then be followed up every 6 months for 4 years. The primary outcome will be any new clinical fracture.

Importance: Fractures in older adults are both costly for health care systems and major contributors to morbidity and mortality. Since there is little evidence that bone-strengthening treatment is effective after a fracture, the results of this study will have a direct impact on the care of fracture patients.

Popular scientific description (Swedish)

Idag inträffar ungefär 95 000 frakturer i Sverige årligen. Risken att drabbas ökar med åldern, delvis på grund av att skelettet blir svagare. Framför allt höftfrakturer, som nästan uteslutande drabbar äldre, är relaterade till ett ökat beroende av andra människor och en kraftigt ökad risk för tidig död, då 25 % av patienterna dör inom ett år. Det är idag farligare att drabbas av en höftfraktur, sett till överlevnad, än både hjärtinfarkt och stroke. Även kotfrakturer ökar risken för tidig död. Många som drabbas har dessutom kroniska smärttillstånd som påverkar livskvaliteten avsevärt.

Det har länge varit känt att personer som drabbas av en fraktur löper hög risk att drabbas av fler frakturer. Det här sambandet skulle kunna utnyttjas av hälso- och sjukvården genom att göra riktade interventioner till äldre människor som drabbats av fraktur, för att på så sätt minska deras risk för nya frakturer. Det här görs inte idag, och mindre än 10 % av de äldre som drabbas av fraktur förskrivs någon form av benstärkande behandling. En viktig bakomliggande orsak är sannolikt att de läkemedel som finns främst har utvärderats på äldre kvinnor med benskörhet och/eller kvinnor med tidigare kotfrakturer. Benskörhet ökar visserligen risken för fraktur, men benskörhet är en diagnos som ställs genom mätning av bentäthet, och låg bentäthet ger inte symptom om inte patienten söker vård efter en fraktur. Dessutom mäts bentäthet vanligtvis inte på samma klinik där frakturen handläggs, och slutligen har primärvården ofta ansvaret för att bedöma ifall benstärkande behandling ska ges. Fallerar något i denna frakturkedja kommer alltså inte patienten att få någon bedömning eller behandling. Därutöver förekommer benskörhet endast hos 20 % av de äldre personer som drabbas av fraktur. Ett alternativ skulle kunna vara att behandla personer med fraktur utan att först mäta bentätheten. Det saknas dock helt kunskap gällande om sådan behandling är effektiv, med undantag för personer med höftfraktur och kotfraktur, som drabbar en minoritet. Till sist saknas i stort sett vetenskapligt belegg för att behandla män med tidigare frakturer, trots att 25 % av alla frakturer drabbar män.

Att studera effekten av benstärkande behandling bland både kvinnor och män som drabbats av andra frakturer än kotfrakturer och höftfrakturer skulle alltså vara av intresse ur många aspekter. Frakturer som drabbar arm, underben och bäcken utgör majoriteten av de frakturer som drabbar äldre. Då de här frakturerna dessutom inträffar vid en lägre ålder än kotfrakturer och höftfrakturer skulle en effektiv behandling kunna minska risken för dessa allvarligare frakturer senare i livet. Enligt svenska nationella register får idag endast 8 % av alla kvinnor och 2 % av alla män med frakturer i arm eller underben någon form av benspecifik behandling.

Utifrån detta avser vi att rekrytera 2 900 män och kvinnor, minst 65 år gamla, med en nyligen genomgången fraktur (förutom patienter med höft- eller kotfraktur, eftersom dessa bör behandlas enligt nuvarande riktlinjer). Deltagarna kommer att lottas till att antingen få zoledronsyra, ett beprövat benstärkande läkemedel, eller placebo (en saltlösning utan effekt på hälsan). Syftet är att undersöka om zoledronsyra minskar risken för nya frakturer.

Frakturer är både kostsamma för vården och orsakar lidande och tidig död bland befolkningen. Eftersom det saknas studier på benstärkande behandling efter de flesta typer av frakturer skulle resultaten av den här studien, oavsett om de visar att behandlingen är effektiv eller inte, kunna tillämpas direkt på de 95 000 äldre personer som årligen drabbas av fraktur i Sverige.

Planned use of research infrastructure

Specify national/international infrastructures funded by the Swedish Research Council, not local core facilities.

Planned use of research infrastructure

No

Research description

Reporting of ethical considerations

There are several ethical aspects that need to be considered in the present study. The risk of side effects is one of these aspects. The study drug, zoledronic acid, has been previously studied in three large placebo-controlled trials with fracture as the main endpoint.¹⁻³ The most common side effects, occurring in 30% of patients, are influenza-like symptoms and musculoskeletal pain lasting for 1-3 days after the infusion.¹⁻³ These symptoms may cause discomfort, but they are not dangerous and can be eased with paracetamol if needed.

Previous research has also found that zoledronic acid and other bone-specific agents can cause atypical femur fractures⁴ and osteonecrosis⁵ of the jaw. However, these side effects have only been reported with an incidence rate of about 1/10,000-1/100,000,⁵ and they are typically found after treatment periods of more than 7 years.^{4,6} Furthermore, osteonecrosis of the jaw is predominantly found in cancer patients, who receive much higher doses of bone-specific agents than do osteoporosis patients.⁵ It should also be noted that zoledronic acid was not found to increase the risk of atypical femur fractures and osteonecrosis of the jaw in the three large trials previously mentioned.¹⁻³ Nevertheless, we will inform participants of potential side effects and instruct them to report signs of them to their study center immediately. Patients will also be interviewed about adverse events every sixth months of follow up.

Another aspect of ethical concern is that some of the patients in the placebo group likely would have received bone-specific treatment if they had not been included in this study. However, according to Swedish national registers, only about 7% of patients in Sweden with the type of fractures that meet our inclusion criteria are actually prescribed bone-specific drugs today.^{7,8} Furthermore, we will exclude individuals with a previous hip fracture or vertebral compression fracture and individuals on corticosteroids, because these patient should receive treatment according to current guidelines.

Finally, there is a patient privacy issue in the recruitment process because we intend to use the Swedish Fracture Register to identify potential participants, who will be contacted by postal mail. These patients have not consented to being contacted by researchers, although they have all consented to the use of their data in research. We have verified with lawyers at the Swedish Fracture Register and Registercentrum Västra Götaland that recruitment through this register is legally acceptable. We also believe it is a lesser invasion of privacy to send letters than to approach patients in emergency wards, where they are in pain and in urgent need of care. Given the very low number of patients currently prescribed bone-specific drugs, we anticipate that the majority of patients will be grateful to receive an invitation to participate.

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The project includes handling of personal data

Yes

The project includes animal experiments

No

The project includes experiments involving human subjects

Yes

Sex and gender perspectives

Sex and gender perspectives in the proposed research

Yes

Motivate your answer

With few exceptions, previous studies on bone specific agents have been conducted in postmenopausal women. No randomized study with clinical fracture as primary endpoint has been performed in men only, although 25% of all fractures occur in men. The lack of studies in men has likely contributed to the fact that women are much more likely to be prescribed bone specific agents than men. Thus, according to data from the Swedish National Patient Register, 8% of all women and only 2% of all men are currently prescribed bone specific agents after a fracture of the arm or lower leg. These differences would not be relevant if women who sustain a fracture have a higher risk of new fracture than men do. However, using data from the Swedish National Patient Register, we found that 9.6% of all men, compared to 10.2% of all women, had a new fracture over the next four years. Thus, the risk of a new fracture is similar men and women. For this reason, we will include both men and women in the present study, and as a secondary objective, we will investigate whether the treatment effect is the same in men and women.

Research plan

See following page for attachment

Effects of Zoledronic Acid After a Fragility Fracture: The Fragility Fracture Trial

Purpose and aims

Fractures in older individuals are costly for health care systems¹ and an important cause of morbidity,² mortality,^{3,4} and reduced quality of life.² A strong risk factor for fracture is having a history of fracture, but only a small minority of fracture patients are prescribed bone-specific agents to prevent new fractures.⁵ This fact is likely influenced by lack of studies investigating the effects of bone-specific agents in patients with a recent fracture, without a bone scan to evaluate coexistent osteoporosis. Therefore, the overall aim of the present double-blind randomized controlled trial is to determine whether zoledronic acid reduces the risk of new clinical fractures in older adults with a recent fragility fracture that has not been evaluated for osteoporosis.

State-of-the-art

Each year, about 95,000 older individuals in Sweden suffer a major fracture.⁶ It is well known that fracture patients, especially older fracture patients, are at high risk of sustaining new fractures.⁷ This fact is an opportunity for health care providers to reduce the high burden of fracture in the population through secondary prevention. However, less than 10% of older adults with a fracture receive some form of bone-specific treatment.⁸ An important reason for the low prescription rate is most probably the lack of trials conducted in this patients with a recently sustained fracture, without measuring the bone mineral density to diagnose osteoporosis.⁹ Thus, the majority of clinical trials of bone-specific agents have been conducted in postmenopausal females with osteoporosis¹⁰ and/or a history of vertebral compression fracture or hip fracture.¹¹ A problem with the focus on osteoporosis is that physicians often have a limited ability to diagnose this condition because of limited access to bone density scanners. Even if access were better, only about 20% of fracture patients actually have osteoporosis.¹² Furthermore, since vertebral compression fractures and hip fractures are associated with substantial mortality,^{3,4} morbidity,² and reduced quality of life,² it would be better if treatment decisions could be made before these serious fractures occur. Finally, although about 25% of fractures occur in men, they have been excluded from most studies of bone-specific agents. These circumstances have likely contributed to the fact that only about 6% of male hip fracture patient receive treatment with bone-specific agents.⁵

Thus, conducting a clinical trial in fracture patients, including both men and women, independent of their bone density, and where the fracture is not of the hip or vertebrae, would be of importance for many reasons. First, fractures of the arm, lower leg, and pelvis constitute the majority of fractures in older individuals.⁶ Second, these fractures occur earlier in life than those of the hip and vertebrae, which is an excellent opportunity to prevent these more serious fractures. Third, according to data from Swedish national registers,⁵ only 6.8% of the patients with a fracture of the arm or lower leg receive treatment with bone-specific agents today (and only 1.8% of men), implying an ample opportunity for improvement. Therefore, the present study will examine whether zoledronic acid reduces the risk of clinical fracture in older men and women with a recent non-hip, non-vertebral fragility fracture.

Significance and scientific novelty

According to Swedish national registers, the incidence of fractures is more than double that of stroke and myocardial infarction, and while the risk of death in cardiovascular disease has decreased over time, it has been constant after hip fracture.⁶ Consequently, hip fractures are today associated with higher mortality than stroke or myocardial infarction.⁶ Although bone-specific drugs are available, these drugs are rarely used in fractures patients, probably for the reasons outlined above. Thus, the present study could fill an important knowledge gap and, if treatment is shown effective, it would simplify secondary fracture prevention because bone density scanning would no longer be necessary.

Recent studies also indicate that bone specific agents may reduce the risk of cancer, cardiovascular disease, and even mortality.^{11,13,14} Our study will examine these events as secondary outcomes. We will also investigate whether zoledronic acid influences the novel outcome of muscle strength. This hypothesis is based on two clinical trials where the bone specific agents, zoledronate and denosumab, were found to decrease the risk of falls.^{11,14} Moreover, there is a known crosstalk between osteocytes and muscle cells, which is mediated by pathways that are influenced by bone-specific agents.¹⁵

Finally, as an exploratory objective, we will investigate whether the effect of zoledronic acid on fractures is modified by physical activity. It is well known that bone-specific agents have different effects on bone density in different individuals. Given that physical loading is necessary for maintaining bone at all ages and decreases the risk of fractures,¹⁶ we hypothesize that zoledronic acid will result in a greater increase in bone density, and therefore a greater decrease in fracture risk, in participants who are physically active.

Preliminary and previous results

This project is a continuation of a previous VR project of mine (Dnr-2016-2584). The aim of that project was to study fracture risks and the use of bone-specific drugs in patient groups that are underrepresented in clinical trials. In a first study,⁸ we found that bisphosphonate use after a hip fracture was associated with a decreased risk of a new hip fracture. Similar associations were found in individuals above 80 years of age and in the cohort at large, which is important because older individuals are most often excluded in clinical trials. These findings were later confirmed in both men and women with a history of any type of clinical fracture,¹⁷ and in individuals taking glucocorticoids.¹⁸ However, these studies all had the limitation of being observational, so they do not provide strong evidence that treatment was indeed effective, which limits their usefulness in clinical practice. Yet, the results support such effectiveness, and they form the scientific basis for the present randomized clinical trial.

As outlined above, the low prescription rates of bone-specific drugs are consistent with the lack of clinical trials in fracture patients. This topic was a second area of interest in my previous VR project. In general, the different studies showed that prescription rates are very low, even in individuals with strong indications for bone specific agents. Thus, only 7.9% of Sweden's 76,000 hip fracture patients between 2006 and 2013 received bisphosphonates (the most commonly used bone-specific agents) after their fracture.⁸ Similar results were found in patients with any clinical fracture (8.4%),¹⁷ with a slightly higher prescription rate among those taking glucocorticoids (12.8%).¹⁸ These studies also showed that only about 2-6% of male fracture patients are prescribed bone-specific agents, although we also have shown that 20-25% of all fractures occur in men.^{4,17}

Finally, we have examined the impact of hip fractures on mortality in two papers. In the first paper, we found that 25% of all patients with hip fracture die within a year.⁴ A particularly high risk was observed in men with trochanteric fractures, which is noteworthy because, as explained above, men are almost never prescribed bone specific agents. In the second paper, we could show that the increased risk of death remains, especially during the first year, after controlling for genetic and familial factors using a twin cohort.¹⁹

Project description

Theory and methods

The primary objective of this study is to determine whether zoledronic acid reduces the risk of new clinical fractures, as compared with placebo, in older adults with a recent non-hip, non-vertebral fragility fracture. Clinical fractures are defined as fractures that comes to medical attention, excluding fractures of the hands, feet, skull, or facial bones.

The secondary objectives are to determine whether zoledronic acid, as compared to placebo:

- is equally effective in reducing fractures in men and women
- reduces the risk of cancer
- reduces the risk of stroke, and myocardial infarction
- reduces the risk of all-cause mortality
- increases muscle strength
- reduces the risk of falls and injurious falls not resulting in fractures

The equality of effects in men is important given the lack of previous studies in men and the resulting low prescription rates, despite strong indications for bone-specific therapy. The objective concerning cancer is based on a recent randomized study where zoledronic acid was found to reduce the risk of cancer in women with osteopenia.¹³ The objectives concerning cardiovascular disease and mortality are based on recent studies that found some evidence for zoledronic acid to reduce cardiovascular disease and mortality.^{13,14} The objectives concerning muscle strength and falls is based on the results of two previous clinical trials that bone-specific agents reduced the risk of falls.^{11,14}

Our study also has two exploratory objectives:

- To investigate whether zoledronic acid has a greater effect on fractures, as compared to placebo, in patients who are physically active.
- To evaluate to what extent the effects of zoledronate are sustained after the scheduled follow up period of 4 years

This study will be a phase IV, multicenter, parallel-group, randomized, double-blind, placebo-controlled trial. We plan to randomize 2,900 participants (see the sample size calculation below) to receive two intravenous infusions of either zoledronic acid (5 mg) or placebo (normal saline), one at baseline and one at 24 months. All participants will also receive monthly oral vitamin D (50,000 IU or 2.5 mg/month), as was given in a recent clinical trial of zoledronic acid.¹³ Zoledronic acid and placebo will be stored in identical containers labeled with a medication number, so that patients, principal investigators, and investigators' staff will all be blinded. Participants will be followed-up every 6 months for 4 years.

Our plan to give patients zoledronic acid at two-year intervals differs from clinical practice, in which it is given once a year. This decision was based on the results of several previous studies. In a recent phase IV trial, zoledronic acid given at 18-month intervals resulted in a reduction in clinical fractures during 6 years of follow up in women with osteopenia.¹³ In another trial, the same authors showed that the effect of a single dose of zoledronic acid on bone mineral density peaked at least 24 months after the infusion.²⁰ Furthermore, a post-hoc analysis of two large clinical trials demonstrated similar reductions in clinical fractures in subjects who had received only 1 versus 3 infusions of zoledronic acid over three years.²¹ Based on these findings, we expect an extended 24-month treatment interval would maximize the beneficial effects of zoledronic acid on fracture, while reducing the risk of side effects.

To be included in this study, subjects must meet the following criteria:

- willing and able to provide written informed consent
- age \geq 65 years
- ambulatory
- community dwelling

- sustained a non-hip, non-vertebral fragility fracture in the past 2 years

Fragility fractures are defined as fractures occurring after a fall from standing height or less. Non-hip, non-vertebral fractures include fractures of the clavicle, upper arm, forearm, ribs, pelvis, femur (excluding hip), or lower leg. Fractures of the face, skull, hands, and feet will be excluded. The limit of no more than 2 years since fracture is based on two considerations. The first consideration is that the risk of sustaining a new fracture is highest soon after the initial fracture,²² so we expect zoledronic acid to have the greatest effect if it is administered soon after the initial fracture. However, setting a short limit would reduce the number of potentially eligible patients, making it harder to recruit. Therefore, the second consideration is pragmatic: the time limit should not be set too short.

Subjects will be excluded from the study if they meet any one of the following criteria:

- History of hip or vertebral fracture
- Undergone bone density scanning since the fragility fracture
- Previous hypersensitivity to a bisphosphonate
- Estimated glomerular filtration rate of <35 ml per minute per 1.73 m² of body surface area
- remaining life expectancy of <1 year, according the investigator's judgement
- Ionized calcium <1.15 mmol/L
- Ongoing treatment for cancer
- Metabolic bone disease other than osteoporosis
- Previous use of bone-strengthening drugs (e.g. bisphosphonate, teriparatide, raloxifene, strontium ranelate)
- Use of systemic glucocorticoids at a dose of ≥5 mg (prednisolone or equivalent) for ≥3 months in the past year
- Use of drugs known to affect bone metabolism (other than those mentioned above) in the past year (e.g. estrogen, antiestrogens, testosterone, anabolic steroids)

Three different strategies will be used to recruit participants. The first and main strategy is to use the Swedish Fracture Register to identify patients who have recently suffered a fragility fracture. These patients will be sent information about the study through postal mail, followed-up by a telephone call to invite them to a screening visit. The second strategy is to use local patient registers, including X-ray registers, to identify fracture patients. In these cases, patients will be contacted in the same way. The third strategy is to provide written information directly to patients in emergency rooms and to patients participating in fracture liaison services (*Swedish: "frakturkedjor"*). This information will also be followed-up by telephone calls to invite patients to a screening visit. We prefer the first two strategies because it is more respectful to send letters than to approach patients directly in emergency rooms, where they are in pain and in urgent need of care. In addition, it would make it easier to recruit the necessary number of participants.

Once a patient has been invited to a screening visit, the procedure is as follows. At the nearest study center, the patient will be given more information about the project, as well as an opportunity to ask questions. The patient's health will be assessed through a questionnaire and a review of his or her medical records. If the patient wishes to participate and no exclusion criterion is met, informed consent will be collected. Blood samples will then be taken for analyses of ionized calcium and creatinine clearance. Body height, weight, and hand-grip strength (if a hand dynamometer is available at the center) will also be measured. The patient will then be sent home with a prescription for oral vitamin D, to be taken monthly at a dose of 50,000 IU/month (1.25 mg/month) for the duration of the trial. The participant will also receive an accelerometer to monitor his or her physical activity for one week, if such devices are available at the center.

One week after the screening visit, the participant will return to the study center. If the results of the blood test do not require exclusion from the study, the participant will be randomized and infused with zoledronic acid or placebo. After this, the patient will be followed-up by telephone every 6 months for 4 years. In these telephone interviews, information will be collected about efficacy outcomes and adverse events. At month 24 however, efficacy outcomes and adverse events will be assessed at the study center and, if new blood tests show no contraindication, the patient will receive a second infusion of zoledronic acid or placebo. No clinic visit is planned for the end of the study, to reduce the burden on investigators. Efficacy outcomes and adverse events will be verified through review of medical records, if this is applicable given the type of outcome or event. In addition to telephone interviews, data about outcomes and adverse events will be collected through a number of registers (the Swedish Fracture Register, the National Patient Register, the Swedish Cancer Register, the Cause of Death Register, SWEDEHEART, and Riksstroke).

Time plan

The study is anticipated to take 6 years to complete. Participant recruitment is planned to start in first quarter of 2021 and finish in the first quarter of 2023. Due to lagging follow-up, the study will end for the primary outcome at the time of the last patient's 4-year follow-up, which is planned to be in the first quarter of 2027.

Project organization

We estimate that we will need for 8-10 study centers with a capacity to recruit approximately 300 participants each. Below is a short description of our organization.

My (Peter Nordström, principal investigator) research group currently has about 15 employees. Our main research project is called Healthy Ageing Initiative (<https://www.healthyageinginitiative.com>), which offers a 3-hour health examination to every 70-year-old in Umeå Municipality. We currently have 800 participants a year, and since the health examination is more extensive than the planned procedure for this project, we would be able to recruit more than 1000 individuals per year to this project. As project leader, I estimate that I will spend 33% of full-time on this project (I have 33% time for research in my position as professor). However, if funding for the project is granted, I plan to negotiate with Region Västerbotten and Umeå University for additional time to work in the project. A PhD student/statistician (Jonathan Bergman) will be able to put in 100% of full time in the project, and we will receive unlimited support from Kliniskt Forskningscentrum at Region Västerbotten.

Below are partners who have agreed to participate in the project, and have resources to set up study centers across Sweden.

- Anna Nordström, adj Professor, senior consultant physician, University Hospital of Northern Sweden, Umeå
- Östen Ljunggren, Professor, senior consultant physician, Uppsala University Hospital
- Johan Niklasson, senior consultant physician, PhD, Sunderby Hospital.
- Miia Kivipelto, Professor, senior consultant physician, Karolinska Institutet and Stockholms sjukhem.
- Mattias Lorentzon, Professor, senior consultant physician, Sahlgrenska University Hospital.
- Kristina Åkesson, Professor, senior consultant physician, Skåne University Hospital.
- Ami Hommel, Professor, Lund University.
- Kristian Axelsson, MD, specialist under training, Skaraborg Hospital.
- Anne Ekdahl, senior consultant physician, PhD, Helsingborg Hospital.

- Margareta Röden, senior consultant physician, Sundsvall Hospital.
- Jörg Schilcher, senior consultant physician, PhD, Linköping University Hospital.

Data analysis and statistics

The study will enroll 2900 patients, of whom 227 will need to sustain a clinical fracture during follow-up for the study to achieve 90% power to detect a 35% reduction in clinical fractures with the log-rank test (2-sided significance level of 5%). This calculation assumes a 4-year fracture risk of 10% in the placebo group and an overall dropout rate of 5% due to withdrawal, where the patient does not consent that their data is used. The details of the calculation can be found under the subtitle Appendix in the end of the research program.

To put the assumptions of the sample-size calculation in perspective, we note that 3 of 4 previous large trials of zoledronic acid had 90% power,^{10,11,23} the fourth had 80% power.¹³ Dropout rates were 7% in women with osteopenia (6-year follow-up)¹³, 11% in men with osteoporosis (1-year follow-up),²³ 16% in trial in women with osteoporosis (3-year follow-up),¹⁰ and 29% in hip-fracture patients (1.9-year median follow-up).¹¹ It should be noted that these drop-out rates were calculated from both deaths and withdrawal, in contrast to in our study. Furthermore, three of the trials were powered to demonstrate effects on clinical fractures, and these showed effects of 27%,¹³ 33%,¹⁰ and 35%.¹¹

The assumed 4-year fracture risk of 10% was derived from data we have previously collected from the Swedish National Patient Register about the Swedish population. We selected adults in Sweden who were aged 65-85 years and who suffered a first fracture of the arm or lower leg in 2006 (ICD-10 codes S42, S52, S82). There were 10,361 such individuals who were not prescribed bone-strengthening treatment over the next 4 years. Their mean age was 74.9 years and 73% were women. Over these 4 years, 10.0% (n=1028) suffered a new fracture, with a similar risk in women (10.2%) and men (9.6%).

Randomization will be done according to a 1:1 permuted-block design using a computerized random-number generator. All randomized patients (i.e., the intention-to-treat population) will be included in an efficacy analysis. For each time-to-event outcome (fractures, death, cancer, and cardiovascular disease), time will be calculated as date of event minus date of randomization plus 1 day (to account for possibility of an event occurring later in the day of randomization). For participants not experiencing the event, time will be set as the longest follow-up time. Time-to-event outcomes will be analyzed using 4-year cumulative incidence curves, estimated using the Kaplan-Meier method. The efficacy of zoledronic acid will be determined on the basis of the log-rank test. The relative effect of zoledronic acid versus placebo will be represented by hazard ratios (with 95% confidence intervals), estimated using Cox regression models. These models will be adjusted for study center and, in a sensitivity analysis, a treatment-by-center interaction term, as recommended by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). To test whether the effects of zoledronic acid differ by sex, a product term between sex and intervention group will be included in the Cox models. The statistical significance of this term (i.e. the presence of multiplicative interaction) will be tested using the Wald test. The proportional-hazards assumption will be assessed using log-minus-log plots and by Wald tests for significance of treatment-by-time product terms. In case of a violation of this assumption, hazard ratios will be computed for time-intervals in which hazard ratios are more stable (e.g. 6-month or 12-month periods).

The occurrence of falls will be analyzed using number and percent affected by 4 years, and efficacy will be determined using logistic regression, adjusted for study center. Change in body height and hand-grip strength will be analyzed using analysis of covariance (ANCOVA), with post-intervention values (at the 24-month follow-up) as the response variable and treatment, center, and baseline values as explanatory variables. In a sensitivity analysis, a

treatment-by-center interaction will be included in the logistic regression and ANCOVA models. If either the post-intervention or the baseline value is missing, the subject will be excluded from the analysis. The assumptions of linearity, constant variance, and normality will be checked using residual plots and normal quantile-quantile plots. Clear violations of these assumptions will be dealt with by transformations of the response or baseline predictor variables. Clear violations of the assumption of constant variance may instead be dealt with using the method of weighted least squares. Outliers will not be removed.

P-values of less than 0.05 and 95% confidence intervals not including 1 will be considered statistically significant. There will be no adjustment for multiple comparisons.

Equipment and need for research infrastructure

All study centers will have access to the required equipment and research infrastructure.

International and national collaboration

National collaboration is central to this project, as it will be conducted at multiple centers across Sweden, from Malmö in the South to Sunderbyn in the North, as described above. With respect to international collaboration, Prof Ian Reid, who has an outstanding experience from previous RCTs,^{13,20} has been of great help with the respect to the development of the research protocol underlying the present study proposal. He has also agreed to be an advisor for the future planning and the carry through of the study.

Other applications or grants

To cover all costs of the project, we have also applied for funding from VR call "Klinisk behandlingsforskning". We also intend to seek funding from FORTE, Umeå University and Region Västerbotten.

Risk-benefit evaluation

The expected main benefit with zoledronic acid is a reduced risk of fractures. Based on previous studies, we expect to see a 35% relative risk reduction, corresponding to a 3.5% absolute risk reduction, in the study population. There are also health economics benefits to consider. Below is an example for hip fractures.

We expect hip fractures to occur in 5% of the population during follow up, with an absolute risk reduction of 1.75% from zoledronic acid (35% relative risk reduction), resulting in a number need to treat of 57 to avoid 1 hip fracture. The cost of the study drug in clinical practice is about 300 SEK for the two injections used in the present study, and about 800 SEK, if including all other costs, e.g. the cost for personnel and laboratory tests. The total cost to avoid one hip fracture is then $800 \times 57 = 45,600$ SEK:

- Expected 4-year absolute risk reduction of hip fracture: 1.75%
- Expected number needed to treat to avoid one hip fracture: $1/0.0175 = 57$
- Cost of two 5 mg doses of zoledronic acid: 2×150 SEK = 300 SEK
- Additional costs (e.g. staff and laboratory tests): 500 SEK
- Total cost of treatment: 800 SEK
- Total cost to avoid one hip fracture: 57×800 SEK = 45,600 SEK

This cost of 45,600 SEK to prevent one hip fracture can be compared to the estimated 100,000 SEK cost of hospitalization for hip fracture and an additional estimated cost of 400,000 SEK for subsequent health-care costs and social care in the first 12 months following the fracture.¹ Thus, there are clear and substantial health economics benefits based only on hip fractures. We expect further cost reductions due to reductions in other types of fractures, as well, and due to increased quality-adjusted life years. There is also some indication from previous studies that zoledronic acid may reduce the risk of cancer, cardiovascular disease, and death.^{10,11,13}

There are also certain potential risks with participating in the present study. The risk of side effects is one of these aspects. Based on the results of three previous trials,^{10,11,13} the most common side effects are influenza like symptoms and musculoskeletal pain lasting for 1-3 days after the infusion, which occurs in 30% of patients. Previous research has also found that bisphosphonates can cause atypical femur fractures and osteonecrosis of the jaw.^{24 25} However, these side effects have only been reported with an incidence rate of about 1/10,000-1/100,000,²⁵ and atypical femur fractures²⁴ and subtrochanteric fractures,²⁶ are typically reported after treatment periods of more than 7 years. Osteonecrosis of the jaw is predominantly found in patients with cancer, who receive much higher doses of zoledronic acid for managing the skeletal complications of cancer.²⁵ It should be noted, that zoledronate has not been demonstrated to increase the risk of these side effects in the three large randomized studies with fractures as endpoint.^{10,11,13} Nevertheless, there will be follow ups to access side effects every sixth month during the total study period of four years.

Another aspect of ethical concern is that some of the patients in the placebo group likely would have received bone-specific treatment if they had not been included in this study. However, as explained above, only about 7% of patients with the type of fractures that will be used to recruit participants for this study are prescribed bone-specific drugs in Sweden today. Nevertheless, we will exclude individuals on long-term glucocorticoid treatment and individuals on other drugs known to affect bone metabolism, as these patients should receive treatment with bone specific agents. All participants will, of course, be free to terminate their participation in the study at any time.

Finally, there is a risk that of invasion of privacy because we intend to contact potential participants through registers of fracture patients. However, individuals that are registered in the fracture register have given their consent for their data to be used in research. We also believe that given the very small number of patients that currently are prescribed bone specific drugs, the majority of patients will appreciate getting the opportunity to participate. In summary, we consider the benefits of conducting this study to clearly outweigh the risks, making the study ethical to perform.

Clinical significance

There are about 95,000 individuals who suffer a fracture in Sweden each year. Especially fractures of the spine and hip are associated with a substantial morbidity, and about 25% of the hip fracture patients die within a year of the event. Bone-specific agents has been shown to reduce the risk of fractures predominantly in postmenopausal women, and in subjects with spine fractures and hip fractures. However, given that these fractures are associated both with a high morbidity and mortality, it would be better if treatment could be initiated before they occur. Furthermore, most patients with fractures do not have osteoporosis, and the most common fractures are other fractures than those affecting the spine and hip. In addition, non-hip, non-vertebral fractures increase the risk of later more severe fractures, they occur at an earlier age than hip fractures and vertebral fractures, and they are rarely considered for treatment today. These facts indicate a high interest to use non-hip, non-vertebral fractures as an inclusion criterion in a randomized controlled trial where the effect zoledronic acid is tested with the primary endpoint of new clinical fractures. The results of the study, irrespectively of whether zoledronic acid is found to be beneficial, will be of great importance for this large patient group and cover an important knowledge gap as to whether older individuals with non-hip non-vertebral fractures can be subject to treatment with bone-specific agents without measuring the bone density. The results of the study will also be of importance for current guidelines, both nationally and internationally.

Appendix

The first step of the sample size calculation is to calculate the number of fractures that need to be observed in the study, because the log-rank test is powered by events rather than

participants. According to the method of Schoenfeld,²⁷ the necessary number of fractures (assuming 90% power, a 2-sided alpha of 5%, and a hazard ratio of 0.65) is

$$\frac{4(Z_{0.05/2} + Z_{0.90})^2}{\ln(0.65)^2} = 227.$$

Here, z_p is the p^{th} percentile of the standard normal distribution and $\ln(\cdot)$ is the natural logarithm.

The second step is to estimate the required number of participants, ignoring any early dropouts due to death or withdrawal from the study. According to Schoenfeld,²⁷ 10% fracture risk in the placebo group and a hazard ratio of 0.65 corresponds to an estimated risk of

$$1 - (1 - 0.10)^{0.65} = 0.06619$$

in the zoledronic acid group. With 227 fractures, the required number of participants becomes

$$\frac{227}{(0.10 + 0.06619)/2} = 2732.$$

The third step is to adjust the sample size of 2732 for dropouts. According to Freedman²⁸ this can be done simply by dividing the sample size by the proportion of non-dropouts:

$$\frac{2732}{1 - 0.05} = 2876.$$

For simplicity, we round this number up to 2900.

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Budget and research resources

Activity level in the project

Role in the project	Name	Percent of full time
1 Applicant	Peter Nordström	30%

Salaries including social fees

Role in the project	Name	Percent of salary				
1 Other personnel without doctoral degree	administratör	100%				
2 Other personnel without doctoral degree	statistiker (Jonathan Bergman)	100%				
Total						
	2021	2022	2023	2024	2025	Total
1	540,000	540,000	540,000	540,000	540,000	2,700,000
2	720,000	720,000	720,000	720,000	720,000	3,600,000
Total	1,260,000	1,260,000	1,260,000	1,260,000	1,260,000	6,300,000

Premises

Type of premises	2021	2022	2023	2024	2025
No information added					

Running Costs

Running Cost	Description	2021	2022	2023	2024	2025	Total
1 läkemedel	zoledronsyra+placebo	968,000	968,000	968,000	968,000	0	3,872,000
Total		968,000	968,000	968,000	968,000	0	3,872,000

Depreciation costs

Depreciation cost	Description	2021	2022	2023	2024	2025
No information added						

Total budget

Specified costs	2021	2022	2023	2024	2025
1 Salaries including social fees	1,260,000	1,260,000	1,260,000	1,260,000	1,260,000
2 Running costs	968,000	968,000	968,000	968,000	0
3 Depreciation costs					
4 Premises					
5 Subtotal	2,228,000	2,228,000	2,228,000	2,228,000	1,260,000
6 Indirect costs	272,000	272,000	272,000	272,000	151,200
7 Total project cost	2,500,000	2,500,000	2,500,000	2,500,000	1,411,200
	Total, applied	Other costs		Total cost	
1	6,300,000	0		6,300,000	
2	3,872,000	0		3,872,000	
3	0	0		0	
4	0	0		0	
5	10,172,000	0		10,172,000	
6	1,239,200	0		1,239,200	
7	11,411,200	0		11,411,200	

Justification of the budget applied for

Zoledronic acid is a substance developed by Novartis Pharma. Given that the patent has ended, Novartis Pharma Sweden has informed us that they have no interest in supporting this study, even if we pay for the investigational products. However, performing this study independent of a pharmaceutical company will increase confidence in the results. We are now in contact with two actors that are working with a proposal for the study (the Swedish Regulatory Services and Apotek Produktion & Laboratorier AB [APL]). APL has estimated a preliminary cost of 800 SEK per infusion bottle, which includes peripheral costs, such as delivery and administrative costs.

In the present study, all costs associated with the recruitment of 2,900 patients will take place during the first two years of the study (2021-2022), and all follow-up visits at a clinic for the second infusion will take place the next two years, i.e. 2023-2024. The costs for other follow-up contacts (i.e., telephone interviews) will be incurred from the time of the first participant's first follow-up contact (mid 2021) and continue until the end of the trial (early 2027).

We estimate that recruitment and follow-up contacts at the clinic will require 6 full-time nurses trained in good clinical practice. The cost of one nurse including LKP is 600,000 SEK/year. The total cost of 6 nurses would then be 14,400,000 SEK during the 4 years of inclusion of patients and follow up visits. However, given that participants will be recruited at different hospitals, we plan to compensate each site per included patient. The total $2 \times 2,900 = 5,800$ visits will then result in a cost of $14,400,000 / 5800 = 2,483$ SEK. Therefore, we will compensate each study center with 2,500 SEK per included patient that is followed up through the study. The total cost will be $2,500 \times 2 \times 2,900 = 14,500,000$ SEK during the first 4 years of the study.

Cost for research nurses: $14,500,000 / 4 = 3,625,000$ SEK/year

Cost for statistician that also during the study including LPK: **720,000 SEK/year**

Cost for study administrator during the study period including LPK: **540,000 SEK/year**

Cost for study drug and placebo, 800 SEK/infusion and 5,800 doses: **1,160,000 SEK/year**

Total cost: $14,500,000 + 6 \times 720,000 + 6 \times 540,000 + 4 \times 1,160,000 = 26,700,000$ SEK

Total cost with 20% overhead: $1.2 \times 26,700,000 = 32,040,000$ SEK.

In the present application, I am applying for funding to cover the cost of the statistician and one administrator. I will also apply for most of the cost for the study drug and placebo.

To cover the remaining costs of the project, we will also apply to the Swedish Research Council's grant for "klinisk behandlingsforskning", FORTE, and from local funds at the universities and regions involved in the study.

Other funding for this project

Funder	Applicant/project leader	Type of grant			Status	Reg no or equiv.
	2021	2022	2023		2024	2025
No information added						

Publications

Applicant's publication list

See following page for attachment

Selection of the ten most relevant papers for the present application:

1. Brännström J, Lövheim H, Gustafson Y, **Nordström P**. Association Between Antidepressant Drug Use and Hip Fracture in Older People Before and After Treatment Initiation. *JAMA Psychiatry*. 2019 Feb 1;76(2):172-179. doi: 10.1001/jamapsychiatry.2018.3679. **IF=15.9. Role: Supervisor. Antidepressants have been associated with fractures previously. We showed that the risk of hip fracture associated with antidepressants is highest before the patient has received the first dose, i.e most likely due to reversed causality.**
2. Vikberg S, Sörlén N, Brandén L, Johansson J, Nordström A, Hult A, **Nordström P**. Effects of Resistance Training on Functional Strength and Muscle Mass in 70-Year-Old Individuals With Pre-sarcopenia: A Randomized Controlled Trial. *J Am Med Dir Assoc*. 2019 Jan;20(1):28-34. doi: 10.1016/j.jamda.2018.09.011. **IF=4.9. Role: Supervisor. The study is a randomized controlled trial where resistance training had great effects on muscle mass in older men and women with pre-sarcopenia.**
3. **Nordström P**, Thorngren KG, Hommel A, Ziden L, Anttila S. Effects of Geriatric Team Rehabilitation After Hip Fracture: Meta-Analysis of Randomized Controlled Trials. *J Am Med Dir Assoc*. 2018 Jun 26. **IF=4.9. Role: PI. The meta-analysis shows effects of geriatric team rehabilitation on physical function and mobility compared to usual rehabilitation at orthopedic departments in patients with hip fracture.**
4. **Nordstrom P**, Pedersen NL, Gustafson Y, Michaelsson K, Nordström A. Risks of myocardial infarction, death, and diabetes in identical twin pairs with different body mass indexes. *JAMA Intern Med*. 2016 Aug 1. doi: 10.1001/jamainternmed.2016.4104. **IF=16.5. Role PI. We show that obesity does not increase the risk of cardiovascular disease, but diabetes, after controlling for genetic factors using a twin model.**
5. Bergman J, Nordström A, **Nordstrom P**. Alendronate use and the risk of nonvertebral fracture during glucocorticoid therapy: a retrospective cohort study. *J Clin Endocrinol Metab* Nov 3. doi: 10.1210/jc.2017-01912. **IF=5.6. Role: Supervisor. In a nationwide cohort study, use of alendronate was associated with reduced risk of fractures in patients on glucocorticoids. The association was stronger for hip fracture and for higher doses of glucocorticoids.**
6. **Nordström P**, Toots A, Gustafson Y, Thorngren KG, Hommel A, Nordström A. Bisphosphonate use after hip fracture in older adults: A nationwide retrospective cohort study. *J Am Med Dir Assoc*. 2017 Feb 23. pii: S1525-8610(17)30006-3. doi: 10.1016/j.jamda.2016.12.083. **IF=5.8. Role PI. The study shows an association between initiation of use of bisphosphonates and reduced risk of hip fracture.**
7. Nyström H, Nordström A, **Nordström P**. Risk of injurious fall and hip fracture up to 26 years before the diagnosis of Parkinson's disease: nested case-control studies in a nationwide cohort. *PLOS Medicine*, DOI: 10.1371/journal.pmed.1001954. 2016. **IF=11.9. Role Supervisor. The study shows that previous hip fractures predict the risk of Parkinsons disease many years before diagnosis.**
8. **Nordström P**, Michaëlsson K, Hommel A, Norrman PO, Thorngren KG, Nordström A. Geriatric rehabilitation and discharge location after hip fracture in relation to the risks of death and readmission. *J Am Med Dir Assoc*, 17:91.e1-7. doi: 10.1016/j.jamda.2015.07.004, 2016. **IF=5.8. Role PI. The study shows a strong reversed association between geriatric rehabilitation and adverse events including mortality in patients with hip fracture.**
9. **Nordström P**, Gustafson Y, Michaëlsson K, Nordström A. Length of hospital stay after hip fracture and short term risk of death after discharge: a total cohort study in Sweden. *BMJ*. 2015 Feb 20;350:h696. doi: 10.1136/bmj.h696. **IF=19.7. Role: PI. The impact of hip fractures on death is high-lighted in a nationwide cohort together with the risk of short length of stay in hospital after hip fracture.**

10. **Nordstrom P**, Sievanen H, Gustafson Y, Pedersen NL, Nordstrom A. High physical fitness in young adulthood reduces the risk of fractures later in life in men: A nationwide cohort study. *Journal of bone and mineral research*. 2013 May;28(5):1061-7. PubMed PMID: 23184669. **IF=6.6. Role: PI. The association between high fitness in adolescence and the later risk of fractures is evaluated.**

Total number of peer reviewed original research papers 2012 and later: 79, H-Index 37.

1. Ballin M, Nordström A. **Nordström P**. Cardiovascular disease and mortality in male twins with discordant cardiorespiratory fitness: a nationwide cohort study. *Am J Epidemiology*, accepted for publication, March 5, 2020.
2. Bränsvik V, Granvik E, Minthon L, **Nordström P**, Nägga K. Mortality in patients with behavioural and psychological symptoms of dementia: a registry-based study. *Aging Ment Health*. 2020 Feb 18:1-9. doi: 10.1080/13607863.2020.1727848. [Epub ahead of print]
3. Berginström N, **Nordström P**, Nyberg L, Nordström A. White matter hyperintensities increases with traumatic brain injury severity: associations to neuropsychological performance and fatigue. *Brain Inj*. 2020 Feb 9:1-6. doi: 10.1080/02699052.2020.1725124. [Epub ahead of print]
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5. Holmquist S, Nordström A, **Nordström P**. The association of depression with subsequent dementia diagnosis: A Swedish nationwide cohort study from 1964 to 2016. *PLoS Med*. 2020 Jan 9;17(1):e1003016. doi: 10.1371/journal.pmed.1003016. eCollection 2020 Jan.
6. Eriksson M, Nääs S, Berginström N, **Nordström P**, Hansson P, Nordström A. Sedentary behavior as a potential risk factor for depression among 70-year-olds. *J Affect Disord*. 2019 Nov 12. pii: S0165-0327(18)32875-1. doi: 10.1016/j.jad.2019.11.035. [Epub ahead of print]
7. Ballin M, Lundberg E, Sörlén N, **Nordström P**, Hult A, Nordström A. Effects of interval training on quality of life and cardiometabolic risk markers in older adults: a randomized controlled trial. *Clin Interv Aging*. 2019 Sep 4;14:1589-1599. doi: 10.2147/CIA.S213133. eCollection 2019.
8. Bergman J, Nordström A, Hommel A, Kivipelto M, **Nordström P**. Bisphosphonates and mortality: confounding in observational studies? *Osteoporos Int*. 2019 Oct;30(10):1973-1982. doi: 10.1007/s00198-019-05097-1. Epub 2019 Jul 31.
9. **Nordström P**, Nordström A. Use of short-acting and long-acting hypnotics and the risk of fracture: a critical analysis of associations in a nationwide cohort. *Osteoporos Int*. 2019 Oct;30(10):1983-1993. doi: 10.1007/s00198-019-05085-5. Epub 2019 Jul 30.
10. Tan ECK, Johnell K, Bell JS, Garcia-Ptacek S, Fastbom J, **Nordström P**, Eriksdotter M. Do Acetylcholinesterase Inhibitors Prevent or Delay Psychotropic Prescribing in People With Dementia? Analyses of the Swedish Dementia Registry. *Am J Geriatr Psychiatry*. 2020 Jan;28(1):108-117. doi: 10.1016/j.jagp.2019.06.008. Epub 2019 Jun 25.
11. Hult A, Johansson J, **Nordström P**, Nordström A. Objectively Measured Physical Activity in Older Adults With and Without Diabetes. *Clin Diabetes*. 2019 Apr;37(2):142-149. doi: 10.2337/cd18-0041.
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Rest of the papers omitted because of lack of space (5 pages allowed)

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Participating researcher's publication list

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Ami Hommel-10 publications

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2. **Hommel, A** Ulander K, Bjorkelund, KB Norrman PO, Wingstrand, H & Thorngren KG. Influence of optimized treatment of patients with hip fracture on time to operation, length of stay, re-operations and mortality within one year. *Injury*. 2008 Oct;39(10):1164-74. doi: 10.1016/j.injury.2008.01.048.
3. Mehaan A, Maher A, **Hommel A**. The International Collaboration of Orthopaedic Nursing: Advancing Nursing Through Technology. *Int Nurs Rev*. 2015 Jun;62(2):203-6. doi: 10.1111/inr.12176.
4. **Hommel A**, Bååth C. A national quality registers as a tool to audit items of the fundamentals of care to older patients with hip fractures. *Int J Older People Nurs*. 2016 Jun;11(2):85-93. doi: 10.1111/opn.12101.
5. Johansen A, Golding D, Brent L, Close J, Gjertsen JE, Holt G, **Hommel A**, Pedersen A B, Rock ND, Thorngren KG. Using national hip fracture registries and audit databases to develop an international perspective. *Injury*. 2017 Oct;48(10):2174-2179. doi: 10.1016/j.injury.2017.08.001.
6. Jonsson M H, Bentzer P, Turkiewicz A, **Hommel A**. Accuracy of the POSSUM score and the Nottingham risk score in hip fracture patients in Sweden - a prospective observational study. *Acta Anaesthesiol Scand*. 2018 Apr 23. doi: 10.1111/aas.13131.
7. Sheehan KJ, Smith TO, Martin FC, Johansen A, Drummond A, Beupre L, Magaziner J, Whitney J, **Hommel A**, Cameron ID, Price I, Sackley C. Conceptual framework for an episode of rehabilitation care. *Phys Ther*. 2019 Mar 1;99(3):276-285. doi: 10.1093/ptj/pzy145.
8. Turesson E, Ivarsson K, Thorngren KG, **Hommel A**. Hip fractures - Treatment and functional outcome. The development over 25 years. *Injury*. 2018 Dec;49(12):2209-2215. doi: 10.1016/j.injury.2018.10.010.
9. **Hommel A**, Magnelli M, Samuelsson B, Schildmeijer K, Göransson K, Sjöstrand D, Unbeck M. Exploring the incidence and nature of nursing-sensitive orthopaedic adverse events: a multicentre cohort study using Global Trigger Tool. *International Journal of Nursing Studies* (2020) 102: Feb, 103473 doi.org/10.1016/j.ijnurstu.2019.103473.
10. Turesson E, Ivarsson K, Thorngren KG, **Hommel A**. The impact of care process development and comorbidity on time to surgery, mortality rate and functional outcome for hip fracture patients: a retrospective analysis over 19 years with data from the Swedish National Registry for hip fracture patients, RIKSHÖFT. *BMC Musculoskeletal Disorders* (2019) Vol 20, Iss 1, 1-8.

Anna Nordström-10 publications

1. Nordström P, **Nordström A**. Use of short-acting and long-acting hypnotics and the risk of fracture: a critical analysis of associations in a nationwide cohort. *Osteoporos Int*. 2019 Oct;30(10):1983-1993. doi: 10.1007/s00198-019-05085-5. Epub 2019 Jul 30. IF=5
2. Ballin M, Lundberg E, Sörlén N, Nordström P, Hult A, **Nordström A**. Effects of Interval Training on Visceral Adipose Tissue in Centrally Obese 70-Year-Old Individuals: A Randomized Controlled Trial. *J Am Geriatr Soc*. 2019 Apr 23. doi: 10.1111/jgs.15919. [Epub ahead of print] IF=4
3. Scott D, Johansson J, McMillan LB, Ebeling PR, Nordstrom P, **Nordstrom A**. Associations of Sarcopenia and Its Components with Bone Structure and Incident Falls in Swedish Older Adults. *Calcif Tissue Int*. 2019 Jul;105(1):26-36. doi: 10.1007/s00223-019-00540-1. Epub 2019 Mar 21. IF=3
4. Nordström A, **Nordström P**. Traumatic brain injury and the risk of dementia diagnosis: A nationwide cohort study. *PLoS Med*. 2018 Jan 30;15(1):e1002496. doi: 10.1371/journal.pmed.1002496. eCollection 2018 Jan. IF=11
5. Nordström P, Toots A, Gustafson Y, Thorngren KG, Hommel A, **Nordström A**. Bisphosphonate use after hip fracture in older adults: A nationwide retrospective cohort study. *J Am Med Dir Assoc*. 2017 Feb 23. pii: S1525-8610(17)30006-3. doi: 10.1016/j.jamda.2016.12.083. IF=5
6. Nyström H, **Nordström A**, Nordström P. Risk of injurious fall and hip fracture up to 26 years before the diagnosis of Parkinson's disease: nested case-control studies in a nationwide cohort. *PLOS Medicine*, DOI: 10.1371/journal.pmed.1001954. 2016. IF=12
7. Nordström P, Michaëlsson K, Hommel A, Norrman PO, Thorngren KG, **Nordström A**. Geriatric rehabilitation and discharge location after hip fracture in relation to the risks of death and readmission. *J Am Med Dir Assoc*, 17:91.e1-7. doi: 10.1016/j.jamda.2015.07.004, 2016. IF=5
8. Nordström P, Gustafson Y, Michaëlsson K, **Nordström A**. Length of hospital stay after hip fracture and short term risk of death after discharge: a total cohort study in Sweden. *BMJ*. 2015 Feb 20;350:h696. doi: 10.1136/bmj.h696. IF=20
9. Nordström P, Michaëlsson K, Gustafson Y, **Nordström A**. Traumatic brain injury and young-onset dementia: A nationwide cohort. *Annals of Neurology*. 2014 Mar;75(3):374-81. IF=10
10. Nordstrom P, Sievanen H, Gustafson Y, Pedersen NL, **Nordstrom A**. High physical fitness in young adulthood reduces the risk of fractures later in life in men: A nationwide cohort study. *Journal of bone and mineral research*. 2013 May;28(5):1061-7. PubMed PMID: 23184669. IF=6

CV

CV - Peter Nordström

Participant researcher: Peter Nordström
Birthdate: 19661005
Gender: Male
Country: Sweden

Doctorial degree: 1996-10-04
Academic title: Professor
Employer: Umeå universitet

Doctors degree

Examination	Organisation	Dissertation title (original language)	Supervisor
30299. Other Clinical Medicine, 1996-10-04	Umeå University, Institutionen för kirurgisk och perioperativ vetenskap+		Ronny Lorentzon

Educational history

Research education

Examination	Organisation	Dissertation title	Name of supervisor
PhD degree, 30299. Other Clinical Medicine, 1996-10-04	Umeå University, Sweden, Institutionen för kirurgisk och perioperativ vetenskap+	Bone mass and physical activity, body constitution and heredity in young age	Ronny Lorentzon

Basic education

Year	Examination
1994	302. Clinical Medicine, University medical Degree, doctor of medicine (MD), Umeå University, Sweden

Professional history

Employments

Period	Position	Part of research in employment	Employer
oktober 2010 - Present	Professor	33	Umeå University, Sweden, Institutionen för samhällsmedicin och rehabilitering+
januari 2010 - september 2010	Senior lecturer	20	Umeå University, Sweden, Institutionen för samhällsmedicin och rehabilitering+
januari 2007 - december 2009	Researcher	20	Umeå University, Sweden, Institutionen för samhällsmedicin och rehabilitering+
januari 2008 - december 2009	Other	0	Västerbotten County Council, Sweden, Geriatriskt Centrum

Period	Position	Part of research in employment	Employer
januari 2005 - december 2006	Other	0	Västerbotten County Council, Sweden, Geriatriskt Centrum
januari 2003 - december 2004	Other	0	Västerbotten County Council, Sweden, Geriatriskt Centrum
januari 2002 - december 2003	Senior lecturer	20	Umeå University, Sweden, Institutionen för samhällsmedicin och rehabilitering+

Merits and awards

Docentur		
Year	Subject	Organisation
2000	30222. Geriatrics	Umeå University, Sweden, Institutionen för samhällsmedicin och rehabilitering+

Supervised persons		
Year	Supervised persons	Role
2015	PhD student, Leslie Bailey, Umeå University, Sweden, Institutionen för samhällsmedicin och rehabilitering+	Main supervisor
2011	PhD student, Fredrik Toss, Umeå University, Sweden, Institutionen för samhällsmedicin och rehabilitering+	Main supervisor
2000	PhD student, Mattias Lorentzon, Umeå University, Sweden, Institutionen för kirurgisk och perioperativ vetenskap+	Main supervisor
2017	PhD student, Gabriel Högström, Umeå University, Sweden, MED Inst. för samhällsmedicin och rehabilitering	Secondary supervisor
2015	PhD student, Undis Englund, Umeå University, Sweden, Institutionen för samhällsmedicin och rehabilitering+	Secondary supervisor
2011	PhD student, Peder Wiklund, Umeå University, Sweden, Institutionen för samhällsmedicin och rehabilitering+	Secondary supervisor
2009	PhD student, Taru Tervo, Umeå University, Sweden, Institutionen för kirurgisk och perioperativ vetenskap+	Secondary supervisor
2007	PhD student, Magnus Högström, Umeå University, Sweden, Institutionen för kirurgisk och perioperativ vetenskap+	Secondary supervisor
1999	PhD student, Ulrika Pettersson, Umeå University, Sweden, Institutionen för kirurgisk och perioperativ vetenskap+	Secondary supervisor
1997	PhD student, Håkan Alfredsson, Umeå University, Sweden, Institutionen för kirurgisk och perioperativ vetenskap+	Secondary supervisor
2011	Postdoc, Taru Tervo, Umeå University, Sweden, Institutionen för kirurgisk och perioperativ vetenskap+	Main supervisor
2020	Postdoc, Andreas Hult, Umeå University, Sweden, MED Inst. för folkhälsa och klinisk medicin	Secondary supervisor
2020	Postdoc, Sabine Björk, Umeå University, Sweden, MED Inst. för folkhälsa och klinisk medicin	Secondary supervisor
2005	Postdoc, Anna Nordström, Umeå University, Sweden, Institutionen för kirurgisk och perioperativ vetenskap+	Secondary supervisor

Research grants awarded in competition

Period	Funder	Project leader	Your role	Sub amount (SEK)	Total amount (SEK)
2017 - 2020	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Peter Nordström	Applicant	0	4 000 000
2015 - 2016	Sweden - Oterh private actors,	Anna Nordström	Co-applicant	0	700 000
2014 - 2017	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Yngve Gustafsson		0	12 144 000
2014 - 2015	Sweden - Oterh private actors,	Anna Nordström		0	4 000 000
2013 - 2015	Sweden - Oterh private actors,	Anna Nordström	Co-applicant	0	4 000 000
2012 - 2014	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Peter Nordström		0	2 100 000

Awards and distinctions

Year	Name of award/distinction
2005	Award for best young researcher within the field of sport science. Sveriges Centralförening för idrottens främjande

Other merits

Period	Type of merit	Description
2014 - 2020	Rikshöft Steering committee	RIKSHÖFT is a national quality registerer patients with hip fractures
2018 - 2020	Member of an expert panel at the Swedish Medical Agency	Contributed to the new guidelines for treatment of osteoporosis and fragility fractures under development from the Swedish Medical Agency.
2008 - 2020	Scientific secretary and member of the board	Member of the steering committee and scientific secretary in the Swedish geriatric society
2015 - 2019	The Swedish dementia register steering committee.	SveDem is a national quality register for dementia disorders. The goal is to improve the quality of care for people with dementia by collecting data and follow up changes patient groups.
2015 - 2017	Expert panel at SBU	Work in an expertpanel at SBU to evaluate evidence for operative treatment in patients with fractures of the arm. The work resulted in a publication issued by the SBU: https://www.sbu.se/contentassets/1b2724fe399f4f1a94916159fa2814c0/behandling_av_armfraktur_hos_aldre_262.pdf The work also resulted in two publications in international journals: Mellstrand Navarro C, Brolund A, Ekholm C, Heintz E, Hoxha Ekström E, Josefsson PO, Leander L, Nordström P, Zidén L, Stenström K. Treatment of humerus fractures in the elderly: A systematic review covering effectiveness, safety, economic aspects and evolution of practice. PLoS One. 2018 Dec 13;13(12):e0207815. Mellstrand Navarro C, Brolund A, Ekholm C, Heintz E, Hoxha Ekström E, Josefsson PO, Leander L, Nordström P, Zidén L, Stenström K. Treatment of radius or ulna fractures in the elderly: A systematic review covering effectiveness, safety, economic aspects and current practice. PLoS One. 2019 Mar 28;14(3):e0214362.

Period	Type of merit	Description
2013 - 2015	Expert panel at SBU	Work in an expertpanel at SBU to perform an meta-analysis concerning evidence for use of multidisciplinary rehabilitation in patients with a hip fracture. The work resulted in publication from the SBU: https://www.sbu.se/contentassets/e6c0d255a3b54ff29cc0cb5af35eddcdb/rehabilitering_aldre_hoftfrakturer_interdisciplinara_team_2015.pdf The work also resulted in a publication in an international high end journal: Nordström P, Thorngren KG, Hommel A, Ziden L, Anttila S. Effects of Geriatric Team Rehabilitation After Hip Fracture: Meta-Analysis of Randomized Controlled Trials. J Am Med Dor Assoc. 2018 Jun 26. pii: S1525-8610(18)30262-7. doi: 10.1016/j.jamda.2018.05.008.

CV - Ami Hommel

Participant researcher: Ami Hommel	Doctorial degree: 2007-05-25
Birthdate: 19570508	Academic title: Associate professor
Gender: Female	Employer: Malmö universitet
Country: Sweden	

Educational history

Research education			
Examination	Organisation	Dissertation title	Name of supervisor
PhD degree, 30305. Nursing, 2007-05-25	Lund University, Sweden, Hälsovetenskaper 314500	IMPROVED SAFETY AND QUALITY OF CARE FOR PATIENTS WITH A HIP FRACTURE Intervention audited by the national quality register RIKSHÖFT	Karl-Göran Thorngren

Basic education	
Year	Examination
1984	30305. Nursing, Degree of Master, Lund University, Sweden
1981	30305. Nursing, Degree of Bachelor of Science in Nursing, Lund University, Sweden

Professional history

Employments			
Period	Position	Part of research in employment	Employer
maj 2019 - Present	Professor, Permanent employment	30	Malmö University
juli 2015 - maj 2019 (Present)	Senior lecturer, Permanent employment	20	Malmö University
juli 2015 - december 2016 (Present)	Senior lecturer, Temporary employment	30	Skåne university hospital, Sweden, Rörelseorganens forskningsavdelning
juni 2007 - december 2013	Senior lecturer, Temporary employment	20	Skåne university hospital, Sweden, Rörelseorganens forskningsavdelning

Merits and awards

Docentur

Year	Subject	Organisation
2012	30305. Nursing	Lund University, Sweden, Hälsovetenskaper 314500

CV - Miia Kivipelto

Participant researcher: Miia Kivipelto	Doctorial degree: 2002-04-16
Birthdate: 19731106	Academic title: Professor
Gender: Female	Employer: Karolinska Institutet
Country: Sweden	

Educational history

Research education			
Examination	Organisation	Dissertation title	Name of supervisor
PhD degree, 30207. Neurology, 2002-04-16	University of Kuopio, Finland, Department of Neurology	'Vascular Risk Factors in Alzheimer's Disease and Mild Cognitive Impairment: A Longitudinal, Population-Based Study'	Hilkka Soininen

Basic education		
Year	Examination	Specialist training
2009	30222. Geriatrics, Authorised Specialist in Geriatrics in Sweden, Karolinska University Hospital, Sweden	Other specialist qualification
2008	30222. Geriatrics, Specialist in Geriatrics, University of Eastern Finland, Finland	Other specialist qualification
1999	30207. Neurology, University medical Degree, doctor of medicine (MD), University of Eastern Finland, Finland	

Professional history

Employments				
Period	Position	Part of research in employment	Employer	Other information
januari 2011 - Present	Professor, Permanent employment	100	Karolinska Institutet, Sweden, NVS (Institutionen för neurobiologi, vårdvetenskap och samhälle)	Professor i Klinisk Geriatrisk Epidemiologi

Period	Position	Part of research in employment	Employer	Other information
januari 2015 - Present	Director of Research, Development and Education (FoUU-chef) & Senior Geriatrician, Theme Aging, Karolinska University Hospital, Permanent employment	30	Karolinska University Hospital	Combined with professor post 30%

Post doctoral assignments

Period	Organisation	Subject
januari 2003 - januari 2005	Karolinska Institutet, Sweden, NVS (Institutionen för neurobiologi, vårdvetenskap och samhälle)	30207. Neurology

Research exchange assignments

Period	Type	Organisation	Subject
januari 2007 - december 2012	Senior researcher Academy of Finland (Periodically on leave)	Academy of Finland	30207. Neurology

Interruptions in research

Period	Description
2012-01-01 - 2012-03-31	Maternity leave (3 months)
2010-02-05 - 2010-04-30	Maternity leave (3 months)

Merits and awards

Docentur

Year	Subject	Organisation
2006	30207. Neurology	University of Eastern Finland, Finland, Neurology

Supervised persons

Year	Supervised persons	Role
2022	PhD student, Malin Aspö, Karolinska Institutet, Sweden, NVS (Institutionen för neurobiologi, vårdvetenskap och samhälle)	Main supervisor
2020	PhD student, Jakob Norgren, Karolinska Institutet, Sweden, NVS (Institutionen för neurobiologi, vårdvetenskap och samhälle)	Main supervisor
2019	PhD student, Anna Rosenberg, University of Turku, Finland, Master programme in Drug Development	Main supervisor

Year	Supervised persons	Role
2016	PhD student, Krister Håkansson, Karolinska Institutet, Sweden	Main supervisor
2014	PhD student, Miika Vuorinen, University of Eastern Finland, Finland, Department of Neurology	Main supervisor
2013	PhD student, Babak Hooshmand, Karolinska Institutet, Sweden, NVS (Institutionen för neurobiologi, vårdvetenskap och samhälle)	Main supervisor
2013	PhD student, Minna Rusanen, University of Eastern Finland, Finland, Department of Neurology	Main supervisor
2012	PhD student, Francesca Mangialasche, Karolinska Institutet, Sweden, NVS (Institutionen för neurobiologi, vårdvetenskap och samhälle)	Main supervisor
2009	PhD student, Alina Solomon, University of Eastern Finland, Finland, Department of Neurology	Main supervisor
2008	PhD student, Suvi Rovio, Karolinska Institutet, Sweden, NVS (Institutionen för neurobiologi, vårdvetenskap och samhälle)	Main supervisor
2006	PhD student, Tiia Ngandu, Karolinska Institutet, Sweden, NVS (Institutionen för neurobiologi, vårdvetenskap och samhälle)	Main supervisor
2021	PhD student, Anders Rydström, Karolinska Institutet, Sweden, NVS (Institutionen för neurobiologi, vårdvetenskap och samhälle)	Secondary supervisor

Research grants awarded in competition				
Period	Funder	Project leader	Your role	Total amount (SEK)
2020 - 2022	CIMED, Sweden - Higher education institutions	Miia Kivipelto	Applicant	1 800 000
2019 - 2022	Forte, Sweden - Other financing agencies and organisations	Miia Kivipelto	Applicant	4 605 000
2019 - 2021	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Miia Kivipelto	Applicant	3 702 000
2017 - 2022	Knut och Alice Wallenbergs Stiftelse, Sweden - Other financing agencies and organisations	Miia Kivipelto	Applicant	15 000 000
2017 - 2022	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Miia Kivipelto	Applicant	19 200 000
2016 - 2019	Not Sweden - International organisations,	Miia Kivipelto	Applicant	3 845 984
2015 - 2020	Not Sweden - International organisations,	Miia Kivipelto	Applicant	8 181 050
2015 - 2020	Sweden - Higher education institutions,	Miia Kivipelto	Applicant	10 000 000
2014 - 2016	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Miia Kivipelto	Applicant	7 193 000
2013 - 2018	European Union (EU),	Miia Kivipelto	Applicant	1 400 000

Awards and distinctions		
Year	Name of award/distinction	Issuer
2019	Arthur C. Cherkin Award	

Year	Name of award/distinction	Issuer
2018	Neuroscientist of the year	Brain Research Society of Finland
2018	Inga Sandeborg's award for Alzheimer Research	Swedish Medical Society
2017	Honorary Professor	Shandon university
2016	Alzheimerfondens Stora Forskningspris	Alzheimerfonden
2016	MetLife Foundations Awards for Medical Research in Alzheimer's Disease: Major Award	American Federation for Aging Research
2015	Waijlit & Eric Forsgrens Prize for prominent Alzheimer's researcher	Waijlit & Eric Forsgren
2013	Karolinska Institutet Skandia's Lennart Levi prize	Karolinska Institutet
2011	Karolinska Institute research groups External research quality evaluation (ERA) (international independent panel): grading 'Excellent'.	Karolinska Institute
2011	Junior Chamber International Award for Ten Outstanding Young Persons of the World	Junior Chamber International Award

Other merits

Period	Type of merit	Description
2002 - 2030	Expert Advisory Member	Expert Advisory Member: OECD Mapping for big data for Alzheimer research meeting March 2014, Paris; Alzheimer Europe, Alzheimer's Disease Internatiol (ADI), and Global Council on Brain Health: A collaborative from America Association of Retired Persons (AARP) (2015-present; Neurodegeneration – Swedish Academy of Science & Academy of Finland (2013-present); G8 Dementia Summit, December 2013, London; Priority group of the National Board of Health and Welfare concerning preventive measures for chronic disorders (2009-2012); Swedish Medical Products Agency at the Workshop on Hyperlipidemia (2002); UK health forum on prevention titled Promoting Brain Health: developing a prevention agenda linking dementia and non-communicable diseases (2014)
2007 - 2030	Evaluation panel member	Evaluation panel member: Swedish Research Council (2011-2014); Regional Ethical Review Board, Stockholm (2009-2014); International Alzheimer's Association (2010-present), KI KID PhD funds applications (2010-present); Half-time seminars (5 times: 2012-2016); Thesis opponent for PhD dissertation (5 times: 2009-2016); External Reviewer for PhD theses (6 times: 2007-2016); Thesis examination committee member (3 times:2007-2016).
2017 - 2026	Founder and Scientific leader	Founding member and scientific leader of the World Wide FINGERS Network, the first global network of multidomain trials for dementia prevention
2016 - 2022	Founder	Founder of Nordic Brain Network (platform to facilitate research collaboration and utilization of infrastructures/resources in Nordic countries) (2009-present); Founding member of the European Dementia Prevention Initiative (EDPI) (2011-present)

Period	Type of merit	Description
2004 - 2020	Principal Investigator & Work Package Leader	Principal Investigator of the following Studies: Cardiovascular Risk Factors, Aging and Dementia (CAIDE) study (2004-present); Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Dementia (FINGER) (2009-present); Multimodal preventive trials for Alzheimer's Disease: towards multinational strategies (MIND-AD) trial project (2015-present); EIT-Health (European Institute of Innovation and Technology (a body of the European Union (EU)) Multimodal strategies to promote a healthy brain in aging: Innovative evidence-based tools (MULTI-MODE) project (2016-present); clinical database GEDOC (for research and quality control) at the Memory Clinic, Karolinska University Hospital, Huddinge (2006-present) Work Package leader: Work Package leader in 2 EU 7th framework collaborative projects: LipiDiDiet—Medical Nutrition in prodromal AD (2009–2013), and Healthy Aging Through Internet Counseling in the Elderly (HATICE) (2013-present)
2011 - 2016	External Opponent for PhD theses	External Opponent for PhD theses - Present - 5 times
2004 - 2016	Steering Committee Member	Steering Committee Member: Svensk Geriatrisk Förening (2014-present); Alzheimer Drug Discovery Foundation (2014-present); Strategic Innovation Agenda (SIA) - Combat Disorders of the Ageing Brain (members from various Swedish Universities and other Stakeholders) (2015-present); The Swedish Council on Technology Assessment in Health Care (SBU) group concerning risk factors for dementia (2004-2005)

CV - Mattias Lorentzon

Participant researcher: Mattias Lorentzon
Birthdate: 19700814
Gender: Male
Country: Sweden

Doctorial degree: 2000-06-03
Academic title: Professor
Employer: Sahlgrenska universitetssjukhuset

Educational history

Research education			
Examination	Organisation	Dissertation title	Name of supervisor
PhD degree, 30211. Orthopaedics, 2000-06-03	Umeå University, Sweden, Institutionen för kirurgisk och perioperativ vetenskap+	Genetic polymorphism and bone density in adolescence	Peter Nordström

Basic education		
Year	Examination	Specialist training
2000	302. Clinical Medicine, University medical Degree, doctor of medicine (MD), Umeå University, Sweden	Specialist qualification as a doctor of medicine

Professional history

Employments

Period	Position	Part of research in employment	Employer	Other information
augusti 2013 - Present	Professor, Permanent employment	100	University of Gothenburg, Sweden, Medicin, inst för	
december 2018 - Present	Universitetssjukhusöverläkare vid geriatriska kliniken, Sahlgrenska universitetssjukhuset, Permanent employment	0	Sahlgrenska University Hospital, Sweden, Osteoporosmottagningen, Geriatriska kliniken	Överläkare vid geriatriska kliniken, Sahlgrenska universitetssjukhuset
maj 2016 - december 2018	Överläkare, Geriatriska kliniken, Sahlgrenska universitetssjukhuset, Permanent employment	30	Sahlgrenska University Hospital	
oktober 2009 - maj 2016	Specialistläkare geriatrisk, Permanent employment	0	Sahlgrenska University Hospital	
januari 2012 - juli 2013	Senior lecturer, Permanent employment	100	University of Gothenburg, Sweden, Medicin, inst för	
april 2010 - december 2012	Researcher, Project employment	100	University of Gothenburg, Sweden, Medicin, inst för	
september 2002 - september 2009	ST-utbildning, Temporary employment	50	Sahlgrenska University Hospital	
september 2005 - september 2009	Assistant professor, Temporary employment	50	University of Gothenburg, Sweden, Medicin, inst för	
augusti 2000 - juni 2002	Allmäntjänstgöring för läkare, Temporary employment	0	Region Sörmland	

Post doctoral assignments

Period	Organisation	Subject
september 2002 - mars 2005	University of Gothenburg, Sweden, Medicin, inst för	30205. Endocrinology and Diabetes

Research exchange assignments

Period	Type	Organisation	Subject
augusti 2019 - februari 2020	Visiting professor	Australian Catholic University, Australia, Melbourne	30222. Geriatrics

Merits and awards

Docentur

Year	Subject	Organisation
2007	302. Clinical Medicine	University of Gothenburg, Sweden, Medicin, inst för

Supervised persons

Year	Supervised persons	Role
2022	PhD student, Berit Larsson, University of Gothenburg, Sweden	Main supervisor
2020	PhD student, Kristian Axelsson, University of Gothenburg, Sweden	Main supervisor
2020	PhD student, Lisa Johansson, University of Gothenburg, Sweden	Main supervisor
2015	PhD student, Anna Darelid, University of Gothenburg, Sweden	Main supervisor
2015	PhD student, Robert Rudäng, University of Gothenburg, Sweden, Medicin, inst för	Main supervisor
2010	PhD student, Martin Nilsson, University of Gothenburg, Sweden, Medicin, inst för	Main supervisor
2023	Postdoc, Daniel Sundh, University of Gothenburg, Sweden	Main supervisor
2022	Postdoc, Helena Johansson, University of Gothenburg, Sweden	Main supervisor
2020	Postdoc, Märit Wallander, Karolinska Institutet, Sweden	Main supervisor
2017	Postdoc, Robert Rudäng, Sahlgrenska University Hospital, Sweden, Geriatriska kliniken	Main supervisor
2016	Postdoc, Martin Nilsson, University of Gothenburg, Sweden, Medicin, inst för	Main supervisor

Research grants awarded in competition

Period	Funder	Project leader	Your role	Total amount (SEK)
2018 - 2022	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Mattias Lorentzon	Applicant	9 000 000
2018 - 2021	Sweden - Municipalities and regional councils,	Mattias Lorentzon	Applicant	5 250 000
2017 - 2017	Not Sweden - Other private actors,	Mattias Lorentzon	Applicant	650 000
2016 - 2016	Sweden - Oterh private actors,	Mattias Lorentzon	Applicant	2 000 000
2015 - 2015	Sweden - Municipalities and regional councils,	Mattias Lorentzon	Applicant	220 000
2013 - 2017	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Mattias Lorentzon	Applicant	6 500 000
2012 - 2016	Sweden - Other governmental agencies,	Mattias Lorentzon	Applicant	15 000 000

Awards and distinctions

Year	Name of award/distinction	Issuer
2016	ASBMR/ECTS clinical debate Golden Femur Award	American Society for Bone and Mineral Research & European Calcified Tissues Society
2014	Erik K Fernströms pris för yngre och särskilt lovande forskare	Eric K Fernströms Stiftelse

Year	Name of award/distinction	Issuer
2008	ESCEO Amgen Fellowship Award, Istanbul, Turkey	The European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO)
2007	John Haddad Young investigator award at the AIMM-ASBMR Meeting, Snowmass, Colorado, USA	American Society for Bone and Mineral Metabolism
2006	Svenska endokrinföreningens årliga forskningspris	Svenska Endokrinföreningen
2005	American Society for Bone and Mineral Research Young investigator award, Nashville, USA.	American Society for Bone and Mineral Metabolism

Other merits		
Period	Type of merit	Description
2019 - 2025	Editorial Board Member, Osteoporosis International	
2013 - 2020	Ledare för Sahlgrenska universitetssjukhusets frakturkedja	Ledare för Sahlgrenska universitetssjukhusets frakturkedja. Sedan 2013 har nya vårdrutiner införts vid sjukhuset. Alla patienter 50 och äldre med osteoporosfraktur erbjuds utredning och preventiva insatser för att förhindra ny fraktur. Vårdrutinen har fyrdubblat andelen frakturpatienter som utreds och behandlas förebyggande efter fraktur.
2012 - 2018	Rektor för en klinisk forskarskola om osteoporos	The Clinical Osteoporosis Research School (a VR-funded research school, 2012-2018)
2014 - 2016	Terapigrupsordförande, Västra Götalandsregionen	Terapigrupsordförande, Västra Götalandsregionen
2013 - 2016	Vårdprocessägare för sekundärprevention av frakturer i Västra Götalandsregionen 2013-2016	Vårdprocessägare för sekundärprevention av frakturer i Västra Götalandsregionen 2013-2016
2011 - 2015	Ordförande i Svenska Osteoporossällskapet	Ordförande i Svenska Osteoporossällskapet 2011-2015
2008 - 2015	Sedan 2008 sakkunnig rörande osteoporos hos Socialstyrelsen	Expert inom nationella riktlinjer för rörelseorganens sjukdomar

CV - Anna Nordström

Participant researcher: Anna Nordström	Doctorial degree: 2004-05-23
Birthdate: 19730831	Academic title: Professor
Gender: Female	Employer: Västerbottens läns landsting
Country: Sweden	

Educational history

Research education			
Examination	Organisation	Dissertation title	Name of supervisor

Examination	Organisation	Dissertation title	Name of supervisor
PhD degree, 30205. Endocrinology and Diabetes, 2004-05-23	Umeå University, Sweden, Institutionen för folkhälsa och klinisk medicin+	Bone mass and physical activity	Tommy Olsson

Basic education	
Year	Examination
2002	30299. Other Clinical Medicine, University medical Degree, doctor of medicine (MD), Umeå University, Sweden
2001	30299. Other Clinical Medicine, Degree of Master, Umeå University, Sweden

Professional history

Employments			
Period	Position	Part of research in employment	Employer
januari 2015 - Present	Other	50	Västerbotten County Council, Sweden, Norrlands Universitetssjukhus
juni 2011 - september 2014	Other	50	Västerbotten County Council, Sweden, Norrlands Universitetssjukhus

Research exchange assignments			
Period	Type	Organisation	Subject
augusti 2017 - juli 2020	Visiting professor	The Arctic University of Norway Tromsø	30302. Public Health, Global Health, Social Medicine and Epidemiology

Interruptions in research	
Period	Description
2004-05-01 - 2011-09-30	ST-tjänstgöring inom Rehabiliteringsmedicin samt föräldraledighet för 2 barn (2004 sam 2006)

Merits and awards

Docentur		
Year	Subject	Organisation
2011	30299. Other Clinical Medicine	Umeå University, Sweden, Idrottsmedicin+

Supervised persons		
Year	Supervised persons	Role
2018	PhD student, Nils Berginström, Umeå University, Sweden	Main supervisor
2017	PhD student, Gabriel Högström, Umeå University, Sweden	Main supervisor

Year	Supervised persons	Role
2016	PhD student, Helena Nyström, Umeå University, Sweden	Main supervisor
2009	PhD student, Peder Wiklund, Umeå University, Sweden, Idrottsmedicin+	Main supervisor
2009	PhD student, Taru Tervo, Umeå University, Sweden, Idrottsmedicin+	Main supervisor
2018	PhD student, Jonas Johansson, Umeå University, Sweden	Secondary supervisor
2016	PhD student, Lisbeth Wikström-Frisén, Umeå University, Sweden	Secondary supervisor
2011	PhD student, Fredrik Toss, Umeå University, Sweden, Idrottsmedicin+	Secondary supervisor

Research grants awarded in competition					
Period	Funder	Project leader	Your role	Sub amount (SEK)	Total amount (SEK)
2017 - 2019	European Union (EU),	Anna Nordström	Applicant	0	10 000 000
2016 - 2018	Sweden - Other governmental agencies,	Anna Nordström	Applicant	0	5 500 000
2015 - 2018	Not Sweden - Governmental agencies,	Anna Nordström	Applicant	0	2 500 000
2014 - 2018	Sweden - Other governmental agencies,	Yngve Gustafson	Co-applicant	0	12 144 000
2014 - 2016	Sweden - Other private actors,	Anna Nordström	Applicant	0	4 000 000
2013 - 2016	Sweden - Other governmental agencies,	Anna Nordström	Applicant	0	3 790 000
2013 - 2015	Sweden - Municipalities and regional councils,	Anna Nordström	Applicant	0	1 350 000
2012 - 2014	Sweden - Other governmental agencies,	Anna Nordström	Applicant	0	2 100 000

Awards and distinctions	
Year	Name of award/distinction
2011	Kungliga Skytteanska Samfundet award to distinguished young researcher at the medical faculty
2011	Young researcher of the year award from Sveriges Centralförening för idrottens främjande

CV - Kristina Åkesson

Participant researcher: Kristina Åkesson	Doctorial degree: 1995-02-03
Birthdate: 19550305	Academic title: Professor
Gender: Female	Employer: Lunds universitet
Country: Sweden	

Educational history

Research education			
Examination	Organisation	Dissertation title	Name of supervisor
PhD degree, 30211. Orthopaedics, 1995-02-03	Lund University, Sweden	Fracture and Biochemical Markers of Bone Metabolism	Karl Obrant

Basic education

Year	Examination	Specialist training
1990	30211. Orthopaedics, University medical Degree, doctor of medicine (MD), The National Board of Health and Welfare, Sweden	Specialist qualification as a doctor of medicine
1985	3. Medical and Health Sciences, University medical Degree, doctor of medicine (MD), The National Board of Health and Welfare, Sweden	Specialist qualification as a doctor of medicine
1983	30299. Other Clinical Medicine, University medical Degree, doctor of medicine (MD), Lund University, Sweden	

Professional history

Employments			
Period	Position	Part of research in employment	Employer
januari 1999 - Present	Överläkare, Permanent employment	50	Skåne university hospital, Sweden, Dept of Orthopedics
april 2007 - Present	Professor	50	Lund University, Sweden, 314785 Ortopedi, Kristina Åkesson
december 1999 - april 2007	Senior lecturer	50	Lund University
september 1995 - oktober 1996	Postdoctoral fellow	100	Loma Linda University
juli 1994 - september 1995	PhD student	100	Lund University
september 1990 - september 1992	Other	20	Lund University

Post doctoral assignments		
Period	Organisation	Subject
september 1995 - oktober 1996	Loma Linda University, USA	30211. Orthopaedics

Merits and awards

Docentur		
Year	Subject	Organisation
1998	30211. Orthopaedics	Lund University, Sweden

Supervised persons		
Year	Supervised persons	Role
2024	PhD student, Patrik Bartosch, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Main supervisor
2020	PhD student, Linnea Malmgren, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Main supervisor
2020	PhD student, Lisa Egund, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Main supervisor
2017	PhD student, David Buchebner, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Main supervisor
2013	PhD student, Mattias Callreus, Lund University, Sweden	Main supervisor

Year	Supervised persons	Role
2011	PhD student, Max Tenne, Lund University, Sweden	Main supervisor
2010	PhD student, My von Friesendorff, Lund University, Sweden	Main supervisor
2010	PhD student, Sofia Lagerholm, Lund University, Sweden	Main supervisor
2006	PhD student, Anna Holmberg, Lund University, Sweden	Main supervisor
2024	PhD student, Sebastian Ström Rönquist, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Secondary supervisor
2023	PhD student, Amar Al-Jabori, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Secondary supervisor
2018	PhD student, Sigrid Isaksson, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Secondary supervisor
2018	PhD student, Susanne Hansson, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Secondary supervisor
2016	PhD student, Johannes Bobjer, Lund University, Sweden	Secondary supervisor
2012	PhD student, Olof Leonardsson, Lund University, Sweden	Secondary supervisor
2004	PhD student, Paul Gerdhem, Lund University, Sweden	Secondary supervisor
2020	Postdoc, Parvaneh Ebrahimi, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Main supervisor
2019	Postdoc, Jai Prakash, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Main supervisor
2019	Postdoc, Vivi Flou Hjorth Jensen, Lund University, Sweden, Kliniska vetenskaper, Malmö 314700	Main supervisor
2016	Postdoc, Maria Herlin, Lund University, Sweden	Main supervisor

Research grants awarded in competition				
Period	Funder	Project leader	Your role	Total amount (SEK)
2019 - 2022	VR, Sweden - Other governmental funding	Kristina Åkesson	Applicant	7 200 000
2019 - 2022	ALF-medel, Sweden - Other governmental funding	Kristina Åkesson	Applicant	5 600 000
2015 - 2018	ALF-medel, Sweden - Other governmental funding	Kristina Åkesson	Applicant	5 200 000
2015 - 2018	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Kristina Åkesson	Applicant	6 000 000
2014 - 2015	Sweden - Oterh private actors,	Kristina Åkesson	Applicant	1 010 000
2013 - 2014	Sweden - Oterh private actors,	Kristina Åkesson		1 082 500
2012 - 2014	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Kristina Åkesson	Applicant	2 400 000
2009 - 2011	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Kristina Åkesson	Applicant	3 525 000
2008 - 2011	ALF-medel, Sweden - Other governmental funding	Kristina Åkesson	Applicant	3 942 000
2008 - 2011	Forte, Sweden - Other financing agencies and organisations	Kristina Åkesson	Applicant	7 055 000

Awards and distinctions

Year	Name of award/distinction	Issuer
2017	ASBMR Plenary Poster award	
2015	Honorary member	Italian Orthopedic Association
2013	ASBMR Plenary Poster award	
2011	ASBMR Presidents poster award and Plenary Poster award	
2009	Royal Physiographic Society Lund	
2006	IOF Young investigator award, Biannual meeting – Anna Holmberg / KÅ senior	
2003	ASBMR Young investigator award, Annual meeting – Paul Gerdhem / KÅ senior	
1995	Olmed Study Award - Swedish Orthopedic Society	
1995	Olmed Charnley Award - Swedish Orthopedic Society	
1995	New Investigator Recognition Award - Orthopedic Research Society (US, Japan, Canada, Europe)	

Other merits

Period	Type of merit	Description
2018 - 2020	Deputy Dean, Faculty of Medicine	Prodekan, Faculty of Medicine, Lund University
2014 - 2018	Editorial board	Osteoporosis International
2009 - 2018	Editorial board	BMC Geriatrics
2012 - 2017	Prefekt	Head of Department of Clinical Sciences Malmö, Lund University
2015 - 2017	ASBMR Task Force	ASBMR Task Force on outcomes after vertebral compression fractures
2010 - 2013	ASBMR Ethics Committee	Ethics committee for American Society for Bone and Mineral Research
2006 - 2012	European Calcified Tissue Society (ECTS), Professional Practice Committee	Member of Professional Practice Committee, European Calcified Tissue Society (ECTS)
2009 - 2012	Chair, Appointment Committee, Faculty of Medicine	Chair Appointment Committee, Faculty of Medicine, Lund University
2005 - 2012	Board member Appointment Committee	Board member Appointment Committee Faculty of Medicine, Lund University – deputy chair 2008-2009
2009 - 2011	Board member, Faculty board	Medicinska fakultetsstyrelsen
2006 - 2009	Swedish Orthopedic Society – Board member	Board member, Swedish Orthopedic Society
2006 - 2008	Vice chairman and Member of the Research Education Committee	Research Education Committee, Faculty of Medicine, Lund University
2004 - 2007	Coordinator, Year 4 undergraduate program	Lund University Medical School

Period	Type of merit	Description
2005 - 2007	Board member, Nominating Committee for Faculty Board	Nominating Committee for Faculty Board, Faculty of Medicine, Lund University
2000 - 2006	Faculty counselor, clinical research post-graduate program, Faculty of Medicine	Faculty counselor for the clinical research post-graduate program, Faculty of Medicine, Lund University
2001 - 2004	Coordinator – Leadership and administration, Faculty of Medicine	Faculty of Medicine, Lund University
2005	ASBMR Working group Biochemical Markers of Bone Metabolism – Board member (2005-present) and chair 2007-2008	American Society for Bone and Mineral Research, Working group for molecular bone markers
2006	IOF Fracture working group (2006-present), chair since 2007	International Osteoporosis Foundation, Fracture working group
2007	IOF – Member of Committee of Scientific Advisors (2007-present)	International Osteoporosis Foundation, Scientific Advisor Committee

Publications

Publications - Peter Nordström

Participant researcher: Peter Nordström
Birthdate: 19661005
Gender: Male
Country: Sweden

Doctorial degree: 1996-10-04
Academic title: Professor
Employer: Umeå universitet

Publications - Ami Hommel

Participant researcher: Ami Hommel
Birthdate: 19570508
Gender: Female
Country: Sweden

Doctorial degree: 2007-05-25
Academic title: Associate professor
Employer: Malmö universitet

Publications - Miia Kivipelto

Participant researcher: Miia Kivipelto
Birthdate: 19731106
Gender: Female
Country: Sweden

Doctorial degree: 2002-04-16
Academic title: Professor
Employer: Karolinska Institutet

Publications - Mattias Lorentzon

Participant researcher: Mattias Lorentzon
Birthdate: 19700814
Gender: Male
Country: Sweden

Doctorial degree: 2000-06-03
Academic title: Professor
Employer: Sahlgrenska universitetssjukhuset

Publications - Anna Nordström

Participant researcher: Anna Nordström
Birthdate: 19730831
Gender: Female
Country: Sweden

Doctorial degree: 2004-05-23
Academic title: Professor
Employer: Västerbottens läns landsting

Publications - Kristina Åkesson

Participant researcher: Kristina Åkesson

Birthdate: 19550305

Gender: Female

Country: Sweden

Doctorial degree: 1995-02-03

Academic title: Professor

Employer: Lunds universitet

Register

Terms and conditions

The application shall be signed by the applicant and also by an authorised representative of the administrating organisation. The representative is normally the head of the department where the research will be carried out, but this is dependent on the administrating organisation's structure.

The *applicant's* signature confirms that

- the information in the application is correct and complies with the Swedish Research Council's instructions
- secondary occupations and commercial ties have been reported to the administrating organisation and that nothing has emerged that breaches good research practice
- the permits and approvals required have been obtained before the research is started, such as permits from the Swedish Medical Products Agency or approval from an ethical review board or an ethical committee on animal experiments
- the applicant will comply with all other conditions applicable to the grant.

The signature of the *administrating organisation* confirms that

- the research or research-supporting activities described can be given room at the administrating organisation during the period and to the extent stated in the application
- the applicant will be employed by the administrating organisation during the period covered by the application
- the administrating organisation approves of the budget in the application
- the administrating organisation will comply with all other conditions applicable to the grant.

The above points shall have been discussed by the parties before the representative of the administrating organisation approves and signs the application.