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How common is osteosarcopenic obesity syndrome (OSO) in an adult population?

Submission date
14/12/2021

Recruitment status
Recruiting

Registration date
17/12/2021

Overall study status
Ongoing

Last Edited
17/12/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In the Western world, a growing part of the adult population is overweight and fails to obtain the recommended level of physical activity required to promote and maintain a good health profile. Furthermore, with increasing age, bone decreases combined with reduced muscle mass and increased fat mass. These changes increase the risk of fractures and the ability to maintain daily physical functions. These conditions and/or diagnoses (e.g., obesity, reduced muscle mass, and bone health) have previously been considered as separate conditions. More lately, these whole-body complex changes all originate from hormonal factors and low-grade inflammation processes causing cellular changes in the bone, muscle, and fat tissue. Therefore, the aim of this project is to examine the prevalence of two and three of these conditions in an adult population.

Who can participate?
Adult patients who are overweight.

What does the study involve?
In this project, we will include measurement of bone mineral density, body composition (e.g., percent of muscle- and fat mass), muscle strength, physical activity – and nutrition habits, blood samples to examine inflammatory markers in addition to questioners including well-being, quality of life, work ability and mental health.

What are the possible benefits and risks of participating?
Typically, reduced bone mineral density (e.g., osteoporosis or osteopenia) is detected after a serious fracture. In this project, we will conduct this measurement and provide a status of the participants` bone health which might motivate participants to improve bone health before serious fracture. Still, the conduct these measurements, the participants are exposed to a low dose of radiated radiation. Importantly, the doses are very low and comparable with a 6 hour flight with an aircraft.

Where is the study run from?
The data collection will be conducted in five test locations in Norway (Sogndal, Bergen, Kristiansand, Fredrikstad and Lillehammer).

When is the study starting and how long is it expected to run for?
January 2021 to March 2032

Who is funding the study?
Western Norway University of Applied Sciences
The Research Council of Norway

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
254084

Study information

Scientific Title
Osteosarcopenic obesity syndrome

Acronym
OSO

Study objectives
1. Examine the prevalence of having osteosarcopenic obesity syndrome (OSO) (e.g., obesity, sarcopenia, and osteoporosis) among overweight or obese women (e.g., BMI over 25 kg/m^2) in Norway

2. Examine the prevalence of having two conditions (sarcopenic obesity and osteopenic obesity) in the same population
3. Examining the age, bone turnover markers, and inflammatory markers as potential moderators and/or risk factors associated with OSO or the dual conditions sarcopenic obesity and osteopenic obesity
4. Examining the well-being, quality of life, work ability, physical activity habits, nutrition habits, muscle strength, muscle quality among individuals with OSO and the dual conditions sarcopenic obesity and osteopenic obesity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/05/2021, Norwegian National Research Ethics committees (REK sør-øst C, Gullhaugveien 1-3, 0484 Oslo, Norway; +47 22 84 55 11; rek-sorost@medicin.uio.no), ref. 254084

Study design
Observational cross-sectional study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Osteosarcopenic obesity syndrome (OSO) (obesity, sarcopenia, and osteoporosis)

Interventions
This project has a cross-sectional design meaning that the participants will only be invited to testing once. Each testing session will last approximately 90 minutes. Overweight (BMI >25 kg /m^2) women over 50 years will be recruited from five testing locations (Lillehammer, Kristiansand, Fredrikstad/Sarpsborg, Bergen and Sogndal). Within a 45-minute drive, these locations include close to 20% of the Norwegian population. All test locations are related to University Colleges and will involve researchers, students and participants from a broad area of Norway.

DEXA is the gold standard to examine bone mass and bone mineral density in addition to measuring lean mass and body fat. Furthermore, the study will include measurements of muscle strength as sarcopenia causes reduced muscle strength, muscle mass and reduced physical performance (gait speed, handgrip strength, one-leg stance, and sit-to-stand chair). Reduced muscle strength and physical performance increase the risk of falls and fractures. Questionnaires including well-being, quality of life, work ability, mental health, physical activity habits, and nutrition habits (RAND-36, PROS, PROQOL, IPAQ- IPAQ, and SarQoL) will be included as these outcomes are often overlooked in epidemiology studies. The questionnaires will provide a broader and more in-depth understanding of how these individuals experience the conditions. Furthermore, to gain greater knowledge of the fat infiltration of the muscles, sub-groups will be invited to undergo magnetic resonance imaging (MRI) of the quadriceps to examine muscle quality (muscle volume divided by the muscle force output) and degree of fat infiltration in the muscle. Accordingly, a subpopulation of the participants will be enrolled in analyses of biomarkers of inflammation and bone turnover using blood samples. In addition to

3000 women being enrolled in this project, the researchers aim to use register data from the HUNT study (n = 22,857), the Tromsø Study (n = 3,100) and 100,000 from the UK biobank which all includes adults with DEXA in addition to as many of the outcomes as described above as possible. By including register data from both sexes, will be able estimate the prevalence of OSO in a Norwegian population and a comparable population in the UK.

Intervention Type
Mixed

Primary outcome(s)
Bone mineral density, lean mass, and body fat measured using DEXA at a single time point

Key secondary outcome(s))
Measured at a single time point:
1. Muscle strength in isometric knee extension and grip strength
2. Muscle mass measured using DEXA
3. Physical performance (gait speed, handgrip strength, one-leg stance, and sit-to-stand chair)
4. Well-being, quality of life, work ability, mental health, physical activity habits, and nutrition habits (RAND-36, PROS, PROQOL, IPAQ- IPAQ, and SarQoL)
5. Muscle quality (muscle volume divided by the muscle force output) and degree of fat infiltration in the muscle measured using magnetic resonance imaging (MRI) of the quadriceps
5. Biomarkers of inflammation and bone turnover measured using blood samples

Completion date
01/03/2032

Eligibility

Key inclusion criteria
1. Overweight (BMI >25 kg/m²) women over 50 years
2. All adults (independent of age or sex) will be included from the biobank databases

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Sex
All

Key exclusion criteria
Aged under 18 years

Date of first enrolment
01/05/2022

Date of final enrolment
01/05/2030

Locations

Countries of recruitment
Norway

Study participating centre
Western Norway University of Applied Sciences
Røyrgata 6
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Sponsor information

Organisation
Western Norway University of Applied Sciences

ROR
https://ror.org/05phns765

Funder(s)

Funder type
University/education

Funder Name
Høgskulen på Vestlandet

Alternative Name(s)
Western Norway University of Applied Sciences, HVL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

All data will be stored on Western Norway University of Applied Sciences (HVL) research servers. The participants' data will not be stored by name, but with an identification code to ensure anonymity. The connection key between the participants and identification code will be stored separately according to the current rules of storage of personal information in research. All participants can ask for insight into which variables are stored.

Western Norway University of Applied Sciences research servers are restricted to Norwegian laws and regulations and the Western Norway University of Applied Sciences regulations. To gain access to the data sets or available data, the Western Norway University of Applied Sciences are working with Norwegian authorities to establish legal procedures and regulation. At the present point, the solution is not completed. Therefore, please use this contact information atle.saeterbakken@hvl.no to gain an update on the process.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available