Musculoskeletal aging in the Geneva Retirees Cohort

Submission date 13/07/2016	Recruitment status No longer recruiting
Registration date 21/07/2016	Overall study status Completed
Last Edited 05/08/2024	Condition category Musculoskeletal Diseases

[] Prospectively registered

[] Protocol

[] Statistical analysis plan

[X] Results

[] Individual participant data

Plain English summary of protocol

Background and study aims

Musculoskeletal aging, leading to osteoporosis (a health condition where the bone becomes brittle and fragile) and sarcopenia (a condition where muscle loses its mass – so it shrinks – and strength), results in falls and fractures that largely contribute to mortality (disease and illhealth) and loss of quality of life in the elderly. In order to provide a more complete understanding of bone and muscle aging and a rationale for targeted interventions (treatments) to prevent falls and osteoporotic (bone)fractures, this study aims at identifying the intrinsic and extrinsic determinants of musculo-skeletal aging, and their contribution to quality of life.

Who can participate?

1036 retired community-dwelling healthy volunteers (men and women) from the Geneva area, at the age of 63-67 (Geneva Retirees Cohort (GERICO)).

What does the study involve?

Each participant in the study attends a study visit every three years to assess their current state of bone and muscle health. These are determined by measuring bone mineral density (measuring the amount of minerals in the bone) and the architecture of the bone (structure), muscle mass, how the muscles function and physical performance. Medical conditions are also noted, as are the number of fractures and falls, the participants nutrient intake and how physically active they are.

What are the possible benefits and risks of participating? Participant will benefit from a comprehensive assessment of their bone and muscle health. No specific risk is expected.

Where is the study run from?

Service of Bone diseases, University Hospitals of Geneva (Switzerland)

When is study starting and how long is it expected to run for? February 2008 to December 2018 Who is funding the study? Geneva University Hospitals and Faculty of Medicine Clinical Research Centre (Switzerland)

Who is the main contact? Dr Emmanuel Biver

Contact information

Type(s) Public

Contact name Dr Emmanuel Biver

Contact details Division of Bone Diseases, Geneva University Hospitals and Faculty of Medicine 4 Rue Gabrielle Perret-Gentil Geneva 14 Switzerland 1211

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Musculoskeletal aging in the Geneva Retirees Cohort (GERICO): a prospective analysis of its determinants and contribution to fractures and quality of life

Acronym

GERICO (Geneva Retirees Cohort)

Study objectives

Predictors of falls and fractures, two major outcomes of osteoporosis and sarcopenia contributing to age-related disabilities and quality of life alterations, would be identifiable at time of retirement.

Ethics approval required

Old ethics approval format

Ethics approval(s)

 Central Ethics Committee on Research on human beings of Geneva University Hospitals, 17/08 /2008, ref: 08-036 (Psy 08-007)
 Central Ethics Committee on Research on human beings of Geneva University Hospitals, 04/05 /2012, ref: 11-256 (Psy 11-031)
 Geneva Cantonal Committee of Research Ethics, 08/07/2015, ref: CER 15-133

Study design

Prospective single-center observational cohort study

Primary study design Observational

Secondary study design Longitudinal study

Study setting(s) Community

Study type(s) Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Musculoskeletal diseases

Interventions

The Geneva Retirees Cohort (GERICO) is a prospective observational cohort study of communitydwelling women and men recruited between 2008 and 2011 at the age of 65±1.4 yrs and followed longitudinally every 3 years after their first visit to assess the determinants of bone and muscle health alterations with aging. A second visit (follow-up 1) was initiated in 2012 and completed in 2014, and a third visit (follow-up 2) is undergoing since August 2015 until 2018.

Participants are assessed at each visit for:

- 1. Medical conditions, fractures and falls history, nutrition, physical activity.
- 2. Bone mineral density and micro-architecture
- 3. Muscle mass and function and physical performance (from second visit)
- 4. Blood tests

Intervention Type

Other

Primary outcome measure

Incident fractures, assessed by face-to-face or and auto-administered questionnaires (clinical fractures) and vertebral fracture assessment (VFA) by DXA (morphometric vertebral fractures) at follow-up 1 (after 3 years) and 2 (after 6 years). Written confirmation (eg, discharge summary, radiologist report) will be requested.

Secondary outcome measures

- 1. Bone phenotype at baseline, follow-up 1 (after 3 years) and 2 (after 6 years)
- 1.1. Bone mineral density using DXA (lumbar spine, hip, radius)
- 1.2. Bone microstructure and strength using high resolution peripheral computerized tomography (HR-pQCT) at distal radius and tibia
- 2. Muscle phenotype at follow-up 1 and 2
- 2.1. Muscle mass and appendicular lean mass adjusted for height mass (kg/m2) using DXA.
- 2.2. Muscle function and physical performance
- 3. Falls in the past years of follow-up 1 and 2
- 4. Genotyping at baseline using exome chip
- 5. Biochemical measurements of bone and mineral metabolism at baseline, follow-up 1 and 2.
- 6. Nutrition (calcium and protein intakes) using a food frequency questionnaire at baseline, follow-up 1 and 2
- 7. Physical activity using a face-to-face administered questionnaire at baseline, follow-up 1 and 2
- 8. Ten-year fracture probability using FRAX tool at baseline, follow-up 1 and 2
- 9. Assessment of quality of life using auto-administered questionnaires at follow-up 2

Overall study start date

12/02/2008

Completion date

31/12/2018

Eligibility

Key inclusion criteria

1. Recently retired workers from the Geneva area

- 2. Both genders
- 3. Age 63 to 67 years
- 4. Rural and urban communities

Participant type(s)

Healthy volunteer

Age group

Senior

Lower age limit 63 Years

Upper age limit 67 Years

Sex Both

Target number of participants 1036

Total final enrolment 853

Key exclusion criteria

- 1. History of cancer treated in the past 5 years
- 2. Chronic renal failure
- 3. Chronic liver or lung disease
- 4. Current corticosteroid therapy
- 5. Primary hyperparathyroidism
- 6. Paget disease of bone
- 7. Malabsorption
- 8. Any neurological or musculoskeletal condition affecting skeletal health

Date of first enrolment 22/07/2008

Date of final enrolment 15/10/2014

Locations

Countries of recruitment Switzerland

Study participating centre Service of Bone Diseases, Department of Internal Medicine Specialties, Geneva University Hospital 4 Rue Gabrielle Perret-Gentil Geneva 14 Switzerland 1211

Sponsor information

Organisation Division of Bone Diseases, Geneva University Hospitals and Faculty of Medicine

Sponsor details 4, Rue Gabrielle Perret-Gentil Geneva 14 Switzerland 1211

Sponsor type Hospital/treatment centre

ROR https://ror.org/01m1pv723

Funder(s)

Funder type Hospital/treatment centre

Funder Name Geneva University Hospitals and Faculty of Medicine Clinical Research Centre

Results and Publications

Publication and dissemination plan

The trialists intend to present preliminary study results at scientific conferences during the course of the study and plan publications in high-impact peer reviewed journals around one year after the end of follow-up.

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
<u>Results article</u>		01/09 /2013		Yes	No
<u>Results article</u>		01/08 /2015		Yes	No
<u>Results article</u>		01/11 /2016		Yes	No
<u>Results article</u>		01/02 /2017		Yes	No
<u>Results article</u>		01/02 /2018		Yes	No
<u>Results article</u>		01/08 /2018		Yes	No
<u>Results article</u>		01/10 /2020	20/07 /2020	Yes	No
<u>Other</u> publications	Development of a personalized fall rate prediction model	30/03 /2023	31/03 /2023	Yes	No
<u>Results article</u>		21/03 /2022	05/08 /2024	Yes	No