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A risk model for osteoporotic fractures reusing CT images acquired for other medical reasons

Submission date
04/11/2025

Recruitment status
No longer recruiting

Registration date
17/11/2025

Overall study status
Ongoing

Last Edited
05/11/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Background and study aims
Osteoporosis (OP) is a silent metabolic bone disease resulting in reduced bone mass and leading to increased rates of bone fragility fractures. OP becomes a major challenge for the quality of life and health care costs of our ageing populations. Areal bone mineral density (aBMD) measured by dual energy x-ray absorptiometry (DXA) is the current standard for diagnosis of OP, but this surrogate of bone strength shows limited sensitivity in predicting fragility fractures. In addition, OP is widely under-diagnosed, and the current fracture risk calculators do not or only partially account for a personalised risk of falls and severity of impact. Accordingly, new strategies and new tools to identify patients at high risk of fractures must urgently be explored. The aim of this project was to develop an integrative fragility fracture prediction model and to validate it with a computer tomography (CT) recycling paradigm that exploits CT examinations of the senior population performed for other medical purposes.
In order to develop and validate the required methods and models, a clinical study that assesses the required variables for fall and fracture risk was conducted.

Who can participate?
Community-dwelling older adults aged 65 years and older who underwent a CT scan at one of the study centers that includes the hip region can participate.

What does the study involve?
The study involves a baseline examination (DXA, HR-pQCT in subgroup, physical performance assessment, questionnaire about daily life and medical history) as well as a follow-up period of 3 years during which incident falls and fractures are recorded via phone calls.

What are the possible benefits and risks of participating?
Individuals who participate in the study benefit from a standard osteoporosis assessment that includes a DXA scan and its evaluation by a medical doctor. No particular risks are expected.

Where is the study run from?
The study was run at two medical centers as well as one academic institution:
1) Service of Bone Diseases, Department of Internal Medicine Specialties, Geneva University Hospital, Switzerland

2) Department of Osteoporosis, Inselspital Bern, University Hospital Bern, Switzerland
3) ARTORG Center for Biomedical Engineering Research, University of Bern, Bern, Switzerland

When is the study starting and how long is it expected to run for?
The first participants were enrolled in February 2021, and the last follow-up calls will be completed by the end of June 2026.

Who is funding the study?
This study is funded by the Swiss National Science Foundation (SNF), grant number 1383584.

Who is the main contact?
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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A fragility fracture integrative risk model using CT recycling

Acronym
AFFIRM-CT

Study objectives
The overall aim of the AFFIRM-CT project was to develop a mechanistic risk model for hip fracture prediction. In this study, bone densitometry as well as risk factors for falls and fragility fractures were assessed.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/07/2020, Commission cantonale d'éthique de la recherche (CCER) Geneve (Rue Adrien-Lachenal 8, Genève, 1207, Switzerland; +41 22 54 65 101; ccer@etat.ge.ch), ref: 2019-01327

Study design

Multicenter observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Fragility fractures and falls in community-dwelling older adults

Interventions
Community-dwelling older adults aged 65 years and older who underwent an abdominal CT scan that included the hip were eligible to participate in the study. Enrolled participants were invited for a single visit to the respective medical centre. During the visit, participants underwent DXA scans of the lumbar spine and hip. At the same time, various variables in the field of medical history, cognitive status and physical performance were assessed. A subgroup was undergoing HR-pQCT scans of the distal tibia and radius. After the examination, individuals were followed up for 36 months, and phone calls were made to assess incident falls and fractures.

Intervention Type
Other

Primary outcome(s)
1. Incident falls, prospectively recorded via phone calls during 3 years of follow-up
2. Incident fragility fractures, prospectively recorded via phone calls during 3 years of follow-up

Key secondary outcome(s))
Measured using patient records (unless otherwise noted) at baseline:
1. Bone imaging modalities:
1.1 Bone mineral density using DXA (lumbar spine, hip)
1.2 Bone microstructure and strength using high-resolution peripheral computerised quantitative tomography (HR-pQCT) images at distal radius and tibia (substudy)
2. Medical history:
2.1 Comorbidities
2.2 Medication
2.3 Falls during the 6 months prior to baseline examination
2.4 History of fractures (all-life)
3. Fall risk factors:
3.1 Physical performance tests (Short physical performance battery (SPPB), hand grip strength, timed up and go)
3.2 Vision acuity with SZB Bailey-Lovie chart
3.3 Physical activity measured with wrist-worn accelerometer (Axivity) and questionnaire
3.4 Cognitive status measured with Mini Mental State Examination (MMSE)
3.5 Fear of falling measured with Falls Efficacy Scale international (FES-I) and questionnaire
4. Soft tissue stiffness measurement over the gerater trochanter performed with the Myoton indentation device

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Individuals aged 65 years and older
2. Community-dwelling older adult
3. Having obtained an abdominal CT including the hip (lesser trochanter of the femur visible)

Participant type(s)
Patient, Other

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
105 years

Sex
All

Total final enrolment
372

Key exclusion criteria
1. Aged <65 years or having a life expectancy of <1 year
2. Nursing home resident
3. Prior hip fracture or hip prosthesis, unilateral or bilateral
4. Suffering from a bone pathology such as bone metastatic cancer, multiple myeloma, Paget's disease, osteogenesis imperfecta
5. Permanently bedridden or in a wheel-chair
6. Have cognitive impairment with incapacity to provide informed consent

Date of first enrolment
01/02/2021

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Bern, Policlinics for Osteoporosis
Imhoof-Pavillon
Bern
Switzerland
3010

Study participating centre
Service of Bone Diseases, Department of Internal Medicine Specialties, Geneva University Hospital
4 Rue Gabrielle Perret-Gentil
Geneva 14
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Study participating centre
ARTORG Center for Biomedical Engineering Research
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Sponsor information

Organisation
Geneva University Hospitals and Faculty of Medicine

Organisation
University of Bern

ROR
https://ror.org/02k7v4d05

Funder(s)

Funder type
Charity

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The data set is currently in preparation to be published on Zenodo.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in German version 4		05/11/2025	No	Yes