Osteoporosis Environmental Exposomics and Radiology Imaging Study: a case-control study*

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Observational invasive

Summary

ID

NL-OMON51044

Source
ToetsingOnline

Brief title
Osteoporosis Exposomics and Imaging

Condition

- Fractures
- Environmental issues

Synonym
Osteoporosis ; brittle bones

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Exposomics, Imaging, Osteoporosis, osteoporotic fractures

Outcome measures

Primary outcome

- Risk effect estimate for lead in fracture case status.

- Mean levels of serum lead.

Secondary outcome

to assess whether other pollutants than the already described heavy metals are

also associated with worse bone health.

Study description

Background summary

Osteoporosis is a multifactorial common metabolic bone disease for which recent studies postulate environmental pollution as an important but largely neglected risk factor.
Bone accumulates up to 90% of heavy metal exposure and ex-vivo bone biopsy studies have linked severely deranged skeletal microarchitecture and elevated heavy metal concentrations in osteoporosis patients, possibly through hormone disruption.

Advanced radiological imaging is the only non-invasive direct technology to further evaluate bone in-vivo.

Study objective

The main objective is to assess the effects of environmental pollution risk factors on bone health in-vivo in patients with osteoporotic fractures.

We hypothesize that higher levels of heavy metals, particularly lead, are detectable in some patients with osteoporotic fractures compared to healthy controls.
We will relate the levels of traces of environmental pollution in patients compared to volunteers regarding imaging parameters of bone quality. Secondary objectives will include to assess whether other pollutants than the already

described heavy metals are also associated with worse bone health.

Study design

Observational cohort study

Study burden and risks

Participants of this study will collect urine and feces, undergo sampling of blood and hair.
Four questionnaires will be filled in at 1 time point, which will take approximately 40 minutes.

The following radiological assessments will be performed at 1 timepoint:
- ultrasound of approximately 10 minutes,
- dual energy X-ray absorptiometry (DXA) bone mineral density measurement of about 15 minutes,
- computed tomography (CT) of approximately 30 minutes
- and a MRI-scans of approximately 45 minutes.

All travel expenses made due to these visits will be reimbursed.

A potential risk of this study involves the X-ray radiation of the CT and DXA scans. The estimated total dose will be 1.11 milliSievert (mSv), of which the estimate from pQCT will be 0.01 mSv, from the photon counting CT 1.0 mSv and the expected dose of the DXA scan will be 0.10 mSv, respectively.

Theoretically, X-ray exposure may have harmful health effects, but this risk is low here with these doses. For subjects involved there is generally no expected immediate direct benefit, except if imaging or environmental exposure assessments yield findings that would be medically actionable.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40

Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 50 years
- To be adequately ambulatory to undergo all imaging and complete the research visits
- Sufficient command of the Dutch language
- Be legally competent to understand informed consent

For disease cases, in addition:
- A history of a bone fragility fracture within the past 2 years but preferably within the last six months diagnosed by radiological imaging

Exclusion criteria

- Patients from whom no written informed consent was obtained
- Fractures of the skull, toes, or fingers
- Fracture by high-trauma mechanism (particularly trauma injury severity score [ISS] >16), such as those including motorized traffic accidents or falls from more than 2 meters height
- Pathological fractures associated with primary or metastatic bone tumors
- Periprosthetic fractures
- Fractures associated with other bone diseases (e.g., Paget*s Disease, fibrous dysplasia)
- Women who are pregnant or lactating

- Participants cannot undergo MRI scans if they have in their body: a

pacemaker, valve prosthesis, certain shunts or certain metals. Persons with a joint prosthesis can mostly undergo MRI scans. These participants can still participate in the remainder of the study

For matched controls, in addition:
- Treatment with medications known to significantly affect bone metabolism in the last year or for >12 months ever, including: hormonal replacement therapy (testosterone or high-dose estrogen), anti-androgens or anti-estrogens, bisphosphonates, teriparatide, denosumab, use of prednisone >7.5 mg daily or the equivalent glucocorticoid for >10 days.
- A history of fractures after age 50 years or in the preceding 5 years

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-02-2023
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	16-08-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL76901.078.21