Nail mineral analysis to study bone metabolism

Published: 07-08-2017
Last updated: 12-04-2024

The objective of the study is to find out whether the concentrations of mineral srelevant to bone metabolism correlate between bone and nails.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON45555

Source
ToetsingOnline

Brief title
NIRVANA

Condition

- Bone disorders (excl congenital and fractures)

Synonym
osteomalacia, osteoporosis

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bone metabolism, instrumental neutron activation analysis, minerals, toenail

Outcome measures

Primary outcome

concentrations of Al, As, Ca, Co, Cr, Fe, Hg, K, Mg, Mn, Zn in both bone and

toenail

Secondary outcome

correlation between concentrations of elements mentioned in the hip and BMD

value of the DEXA

Study description

Background summary

About 800.000 patients are known with osteoporosis and an increased fracture risk in the Netherlands. More than 80.000 fractures per year can be attributed to fragile bones. This not only causes pain, discomfort, sometimes physical limitations but also absence of work, admissions to hospitals, surgery, rehabilitation programs and costs for society. In the elderly there is even a 1 year mortality rate of 25% after a hip fracture. Currently osteoporosis is diagnosed after a fracture and there are hardly programs actively applied to identify high risk patients. Diagnosis is made by DEXA scanning and although more accurate techniques are available they are time consuming, sometimes invasive and costly, so not suited for routine use. So called bone markers in blood and urine have limited value. Best information can be obtained by bone biopsy, but this is a painful, invasive procedure and therefore not used in clinical practice except for research. So there is a need for a simple, non invasive and reliable method to study bone status and bone mineralization, that can be used in research, practice and that can monitor changes induced by interventions (food, drugs).
Nails show some resemblance to bone and are located near bone sometimes having the same vascular supply system. Therefore it can be hypothesized that changes in the supply of minerals to bone will also be reflected in the nail. Some studies have looked at minerals in nail and their correlation to bone status, but their outcomes are conflicting. No study has been performed that compared within the same individual the mineral content of the nail and bone. This is the rationale for the NIRVANA study to do exactly that.

Study objective

The objective of the study is to find out whether the concentrations of mineral srelevant to bone metabolism correlate between bone and nails.

Study design

The study will be performed in patients on the waiting list for hip replacement surgery. They have been seen on the out patient department of orthopedic surgery and are informed by the surgeon about the study. They will get information about the study and will be invited to come to the research department for further information. In case they decide to participate they sign an informed consent letter and nailclipping will be performed. Furthermore a questionnaire will be filled in. At the time of the planned surgery a part of the removed hip bone will be taken and will be send together with the nail to the RID department of the Technical University Delft. Minerals will be measured there with instrumental neutron activation analysis.

Study burden and risks

Apart from the nailclipping and an extra visit to the hospital taking about 30 minutes there are no extra burdens for the patient related to this study

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

planned for hip replacement

Exclusion criteria

other bone disorders than osteoporosis
with congenital or acquired nail disorders

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	07-08-2017

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL60581.100.17