Assessment of Bone Quality by Microindentation in Patients with Bone Diseases

Published: 08-05-2013
Last updated: 24-04-2024

1. To explore the validity and usefulness of Bone Microindentation Technique (BMT) in the assessment of bone quality in patients with osteoporosis and a spectre of bone diseases characterised with (localised) increased bone turnover. 2. To study the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Parathyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON43830

Source
ToetsingOnline

Brief title
microindentation in bone diseases

Condition

- Parathyroid gland disorders
- Fractures

Synonym
nvt

Research involving
Human

Sponsors and support

Primary sponsor: Endocrinologie
Source(s) of monetary or material Support: via lopende studie naar fibreuze dysplasie

en osteoporose

Intervention

Keyword: Bone, Bone quality, Osteoporosis

Outcome measures

Primary outcome

Main study parameters/endpoints: Compare the validity of microindentation measurements with that of BMD measurements as predictor for bone strength as translated by prevalent fractures in the case of patients with osteoporosis

Secondary outcome

.to evaluate the ability of BMT measurements in patients treated with Bisphosphonates, particularly in the longterm, and to predict the role of local increasement in bone turnover in altering bone quality in localised bone diseases such as Paget disease of bone and fibrous dysplasia.

Study description

Background summary

Low bone mass is not the only determinant of bone fragility and the strength and integrity of the skeleton depend also on other properties of the bone tissue, collectively termed bone quality. There is currently no available method to assess the mechanical competence of bone in humans in vivo.
It is known that patients who receive treatment with anti-osteoporosis medication sustain less fractures compared to those who receive other treatment than anti-osteoporosis medication. However, the increase in bone mass as measured by DXA only explains 30% of the decrease in fracture risk, indicating that other component of bone strength also signficantly contribute to this decrease in fracture risk.

Study objective

1. To explore the validity and usefulness of Bone Microindentation Technique

(BMT) in the assessment of bone quality in patients with osteoporosis and a spectre of bone diseases characterised with (localised) increased bone turnover.
2. To study the relationship between known determinants bone strength, such as Bone mineral densitymeasurement as measured by DXA (BMD) and biochemical markers of bone turnover and the BMT .
3. To assess the validity and usefulness of BMT in the follow up of osteoporosis patients started on anti-osteoporotic medication for 18-24 months.
4. To assess the changes in BMT in patients who received other treatments than anti-osteoporotic medication 18-24 months after treatment initiation.

Study design

Case-Control study
Prospective follow-up

Study burden and risks

Except for the additional measurement of microindentation, all laboratory and radiological investigations are part of the routine evaluation of patients. No extra visit to the outpatient clinic will be required. The microindentation measurement will be performed during the regular, preplanned appointment at the outpatient clinic. The time required for the BMT measurement is 10 minutes, the procedure is performed under local anesthesia and is associated with minimal discomfort for the patient.

Contacts

Public
Selecteer

albinusdreef 2
leiden 2332 AC
NL
Scientific
Selecteer

albinusdreef 2
leiden 2332 AC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

>18 years with osteoporosis, osteopenia, with and without fractures or normal bone mass with fractures or metabolic bone diseases

Exclusion criteria

* Active infection of the measurement site.
* Recent fracture of the tibia

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:	Recruitment stopped
Start date (anticipated):	25-06-2013
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	11-02-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	07-10-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	25-09-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	12-05-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	05-10-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL42277.058.12

Study results

Date completed: 01-12-2018

Actual enrolment: 214

Summary results
Trial is onging in other countries