Assessment of Bone Material Strength by Microindentation in vivo after Fracture or Surgery-related Immobilization

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To compare Bone Material Strength of the tibia at the side of a fracture or arhtrodesis with that of the opposite tibia in patients who had been immobilized for at least 6 weeks after a recently sustained fracture of the ankle of calcaneus or after...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine and glandular disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON43556

Source
ToetsingOnline

Brief title
BMS after Immobilization

Condition

- Endocrine and glandular disorders NEC
- Fractures
- Bone and joint therapeutic procedures

Synonym
immobilization, material properties of bone

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Centrum van Botkwaliteit

Intervention

Keyword: Bone Strength, Immobilization, Microindentation

Outcome measures

Primary outcome

BMS

Secondary outcome

not applicable

Study description

Background summary

The process of bone remodelling provides means of maintaining a constant mineral content and bone microarchitecture. The response of bone remodelling to loading and unloading has been extensively studied in animal models that demonstrated profound changes in bone mass and microarchitecture. In clinical practice, bone loss is documented in patients with a stroke, spinal cord injury and after prolonged bed rest or immobilization. It has become clear that low bone mass is not the only determinant of bone fragility and that the strength and integrity of the skeleton also depend on other properties of bone tissue, collectively termed bone quality. We hypothesize that patients also experience a significant loss of bone quality during immobilization after a recently sustained fracture or arthrodesis. Whereas Bone Mineral Density (BMD) could be investigated with absorptiometry and microarchitectural changes with High Resolution peripheral Quantitative Computer Tomography (HRpQCT), techniques for the assessment of material properties of bone in vivo were unavailable. Recently, a minimally invasive technique for the measurement of micro-hardness of bone was introduced. With this technique, an indenter is impressed into the surface of the tibia of the test specimen using a known low applied load and the hardness of the specimen is thereby calculated. This microindentation in vivo technique is currently tested in patients with and without a fracture in our hospital.
There is no information on the effect of immobilization and mobilization on BMS as measured by the microindentation in vivo technique.

Study objective

To compare Bone Material Strength of the tibia at the side of a fracture or arhtrodesis with that of the opposite tibia in patients who had been immobilized for at least 6 weeks after a recently sustained fracture of the ankle of calcaneus or after arthrodesis surgery.
To assess whether Bone Material Strength recovers by mobilization in patients who had been immobilized for at least 6 weeks after a recently sustained fracture of the ankle of calcaneus or after arthrodesis surgery

Study design

Prospective study, case-control study

Study burden and risks

The time required for each measurement is 10-15 minutes. There is a small chance that the measurements may resul in a haematoma or local infection at the measurement site.

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

• Age above 50 years
• Recent fracture of the ankle or calcaneus or arthrodesis surgery of the foot
• Requirement of >= 6 weeks immobilization after a recently sustained fracture of the ankle or calcaneus or arthrodesis surgery of the foot

Exclusion criteria

• Metabolic bone disease other than osteoporosis
• Active infection of the measurement site
• Recent fracture of the tibia
• Untreated endocrine disease, including hypogonadism

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2015
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO Date:	27-03-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-01-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL52221.058.15