

Assessment of Bone Material Strength by Microindentation in vivo in Patients with Acromegaly

Published: 17-11-2014

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To assess Bone Material Strength (BMS) in patients with acromegaly with fractures and without fractures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON40686

Source

ToetsingOnline

Brief title

BMS in Acromegaly

Condition

- Hypothalamus and pituitary gland disorders
- Fractures

Synonym

bone mechanical properties, vertebral fracture

Research involving

Human

Sponsors and support

Primary sponsor: Endocrinologie

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

Intervention

Keyword: Acromegaly, Bone, Bone strength, fractures

Outcome measures

Primary outcome

BMS

Secondary outcome

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Study description

Background summary

Bone mass is an important determinant of bone fragility, but the strength and integrity of the skeleton also depends on other properties of bone tissue, collectively termed bone quality. We have showed recently that in a well-defined cohort of acromegaly patients the prevalence of vertebral fractures is very high, despite long-term biochemical control of GH excess and normal mean bone mineral density. In addition, 20% of patients showed progression of vertebral fractures during long-term control. BMD measurements are not a good predictor of fracture risk in this patient group. We postulate that this apparent high vertebral fracture risk is due to alterations in bone quality rather than changes in bone mass. To date there is no standard method to assess the mechanical competence of bone in humans in vivo. The Universities of California and Barcelona have jointly developed a novel, minimally invasive technique that can specifically measure the micro hardness of bone tissue. This technique, named microindentation, generates information on bone tissue properties that which are not captured by BMD measurements. This technique is fully operational in our department (in a clinical research setting)

Study objective

To assess Bone Material Strength (BMS) in patients with acromegaly with fractures and without fractures.

Study design

prospective study, case-control

Study burden and risks

Except for the additional measurement of microindentation, all laboratory and radiological investigations are part of the routine evaluation of patients 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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

patients with Acromegaly and
• Age above 18 years

- Available data on acromegalic disease, tumor characteristics
- Stable hormone situation for 3 months

Exclusion criteria

- Active infection of the measurement site.
- Recent fracture of the tibia.
- Underlying metabolic bone disease, including vitamin D deficiency.
- Untreated 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): 12-02-2015

Enrollment: 70

Type: Actual

Ethics review

Approved WMO

Date: 17-11-2014

Application type: First submission

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	NL50130.058.14