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

Published: 17-11-2014 Last updated: 22-04-2024

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

1 - Assessment of Bone Material Strength by Microindentation in vivo in Patients wit ... 25-05-2025

Intervention

Keyword: Acromegaly, Bone, Bone strength, fractures

Outcome measures

Primary outcome

BMS

Secondary outcome

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 guality. 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 tissu. 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

Public Selecteer

albinusdreef 2 leiden 2332 AC NL **Scientific** Selecteer

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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

3 - Assessment of Bone Material Strength by Microindentation in vivo in Patients wit ... 25-05-2025

- 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
Туре:	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 CCMO ID NL50130.058.14