Bariatric surgery, bone marrow fat and bone mineral density

Published: 29-01-2015
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The objective of the study is to investigate vertebral bone marrow fat fraction and bone mineral density during surgery induced weight loss.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone, calcium, magnesium and phosphorus metabolism disorders
Study type	Observational invasive

Summary

ID

NL-OMON43737

Source
ToetsingOnline

Brief title
FatBar

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders
- Bone disorders (excl congenital and fractures)

Synonym
Osteoporosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bariatric surgery, bone marrow fat, bone mineral density, obesity

Outcome measures

Primary outcome

* Vertebral bone marrow fat fraction measured by quantitative chemical shift imaging (QCSI)

* Vertebral volumetric bone mineral density measured by quantitative computed tomography (QCT)

Secondary outcome

* Bone turnover markers (CTx, P1NP, osteocalcin), vitamin D, PTH, calcium, leptine, adiponectine

Study description

Background summary

The prevalence of obesity worldwide has increased significantly and recent data show that obesity and poor bone health coexist. While treatment of obesity is associated with improved health outcome, it induces detrimental effects on bone health. These data are difficult to interpret due to difficulties in the accuracy of bone mineral density measurements in morbid obesity and during weight loss.
One of the potential mechanisms by which obesity might negatively affect bone is via bone marrow fat. Bone marrow fat is an unique component of the bone marrow cavity that is functionally distinct from and not subject to the same regulation as subcutaneous- and visceral fat depots. To date, no study has investigated bone marrow fat changes in patients following bariatric surgery. Therefore we will investigate changes in bone mineral density and bone marrow fat following weight loss in subjects who undergo bariatric surgery.

Study objective

The objective of the study is to investigate vertebral bone marrow fat fraction

and bone mineral density during surgery induced weight loss.

Study design

Longitudinal study

Study burden and risks

Subjects will visit our research unit four times in 15 months: two baseline measurements (3 months and 2 weeks prior to surgery), and two post-operative measurements (3 and 12 months post-operatively). Each visit a venous blood sample will be drawn and bone mineral density and vertebral bone marrow fat fraction will be measured by QCT and QCSI, respectively. As the dose equivalent per QCT scan amounts to 1.2 mSv, the total dose equivalent of the participants will be 4.8 mSv for the total study period (IRCP category IIb). The QCSI procedure is a non-invasive, non-ionizing imaging technique without contrast administration. This procedure will take approximately 30 minutes per procedure. Risks associated with venous blood sampling are negligible. The total volume of blood samples from the entire protocol over 15 months will not exceed 200 mL. The subjects included in this study will not directly benefit from the results. However, the participation of the subjects will potentially benefit other people undergoing bariatric surgery in the future; therefore altruistic motives could represent a personal benefit.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Female sex
* Age: 50 years and older
* Postmenopausal
* Scheduled for Roux-en-Y gastric bypass (RYGB)
* Able to fit on MRI table

Exclusion criteria

* Contraindications to MRI scanning as determined by a standard checklist
* Use of bone-modifying or adipose tissue-modifying drugs
* Bone / bone marrow diseases
* Diseases or medication known to have an effect on bone marrow fat

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	12-06-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	29-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23764
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51696.018.14
OMON	NL-OMON23764