Weight loss surgery and changes in bone marrow fat and bone mass.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23764

Source
Nationaal Trial Register

Brief title
FatBar

Health condition

Obesity
Surgery induced weight loss
Osteoporosis

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: Academic Medical Center, Amsterdam

Intervention

Outcome measures

Primary outcome

* Vertebral bone marrow fat fraction measured by QSCI

* Vertebral bone mineral density measured by QCT

Secondary outcome

Bone turnover markers (CTx, P1NP, osteocalcin), 25-hydroxy vitamin D, parathyroid hormone, calcium, albumin, phosphate, alkaline phosphatase, creatinin, complete blood count (CBC), reticulocytes, leptin, adiponectin

Study description

Background summary

Bone marrow fat and bone mineral density are inversely correlated. Greater bone marrow fat is also associated with fractures. Bone marrow fat is regulated differently from visceral and subcutaneous fat. In rodents, caloric restriction results in high bone marrow fat. However, little studies have been published that examined the effects of weight loss on bone marrow fat in humans.

Study objective

Energy restriction by bariatric surgery in obese women increases bone marrow fat and decreases bone mass.

Study design

* 3 months and 2 weeks pre-operative

* 3 and 12 months post-operative

Intervention

Roux-en-Y gastric bypass

Contacts

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Eligibility criteria

Inclusion criteria

* Female sex

* Age: 18-55 years50 years and older

* Postmenopausal

* Scheduled for Roux-en-Y gastric bypass

* Able to fit on MRI table

Exclusion criteria

* Contraindications to MRI scanning

* 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:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-02-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43737
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4951
NTR-old	NTR5056
CCMO	NL51696.018.14
OMON	NL-OMON43737

Study results