Estrogen and bone marrow adiposity.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21671

Source
NTR

Brief title
E2BMFat part 2

Health condition

Osteoporosis

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The role of estrogen in dynamic changes in bone marrow adiposity these changes.

Secondary outcome

NA

Study description

Background summary

Bone marrow consists mainly of bone cells, fat cells and hematopoietic cells. The gradual decrease of bone and hematopoietic fraction and the increase of fat fraction in the bone marrow with ageing and the same rapid changes following menopause have long been recognized. A recent and unexpected observation is that these parameters show dynamic changes over the course of days during a normal menstrual cycle. A common denominator for both phenomena might be estrogen status.

Study objective

Estrogen plays an role in the dynamic changes in bone marrow adiposity.

Study design

Study duration of 6 weeks, with intervention form day 14 to 28.

MRI to measure BM adiposity and bloodsamples at day 0/7/14/21/28/35/42.

Intervention

Estrogen (Zumenon 1dd 2 mg) day 14 to day 28

Contacts

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Eligibility criteria

Inclusion criteria

Postmenopausal women

Exclusion criteria

• contraindications to MRI scanning as determined by a standard checklist

• use of bone-modifying or adipose tissue-modifying drugs

• bone/adipose tissue/bone marrow diseases

• contraindications to estrogen treatment (history of hormone-sensitive cancer, VTE, unexplained vaginal bleeding, endometrial hyperplasia, endometriosis, arterial thrombo-embolic diseases, acute hepatic disease or liver enzyme disorders, porfyria or known hypersensitivity to components of zumenon)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2014
Enrollment:	6
Type:	Actual

Ethics review

Positive opinion
Date: 16-04-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39889
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4390
NTR-old	NTR4521
CCMO	NL40171.018.12
OMON	NL-OMON39889

Study results

Summary results
NA