Dynamic Changes in Bone Marrow Adiposity and the Role of Estrogen

Published: 18-06-2012
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To investigate the dynamic changes in bone marrow adiposity during the menstrual cycle as assessed by Dixon*s Quantitative Chemical Shift Imaging (QCSI) measurements and to determine the role of estrogen in these changes.

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

Summary

ID

NL-OMON39889

Source
ToetsingOnline

Brief title
Estrogen and changes in bone marrow adiposity

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders

Synonym
osteoporosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: bone, bone marrow adiposity, estrogen, menstrual cycle

Outcome measures

Primary outcome

The main study parameters are the dynamic changes in bone marrow adiposity as assessed by QCSI measurements and the correlation of these changes to changes in hormones involved in the menstrual cycle (follicle stimulating hormone, luteinizing hormone, progesterone and estradiol).

Secondary outcome

NA

Study description

Background summary

Bone marrow (BM) bone volume and BM adipose tissue volume show an inverse correlation associated with age and menopausal status. 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

To investigate the dynamic changes in bone marrow adiposity during the menstrual cycle as assessed by Dixon*s Quantitative Chemical Shift Imaging (QCSI) measurements and to determine the role of estrogen in these changes.

Study design

Part 1: Observational cohort study
Part 2: Intervention trial

Intervention

Part 1: no intervention
Part 2: administration of estrogen (Zumenon 1dd 2 mg) during 14 days

Study burden and risks

Estrogen treatment is associated with an increase in hormone-sensitive cancers, cardiovascular disease (CVD) and venous thrombo-embolism (VTE). However, large meta-analyses confirm that these effects occur after prolonged treatment (>1 year), whereas this study discontinues treatment after 14 days. Therefore the risks seem insignificant. The QCSI procedure is a non-invasive, non-ionizing imaging technique without contrast administration. This procedure will be performed 7 or 9 times and will take approximately 30 minutes per procedure. Venous blood sampling will be performed 7 or 9 times and the total amount of blood will not exceed 250 ml. Risks associated with venous blood sampling are negligible. Dual energy X-ray absorptiometry will be performed 3 times, the radiation exposure poses a negligible risk.

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

female sex
regular menstrual cycle and age 18 to 50 years OR 1-5 years postmenopausal

Exclusion criteria

contraindications to MRI scanning
use of bone-modifying or adipose tissue-modifying drugs
use of hormonal contraception
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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2012
Enrollment:	21
Type:	Actual

Ethics review

Approved WMO Date:	18-06-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2014
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: 21671
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL40171.018.12
OMON	NL-OMON21671