The nervous system, estrogen and osteoporosis.

No registrations found.

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

Summary

ID

NL-OMON25589

Source
Nationaal Trial Register

Brief title
E2Bone

Health condition

osteoporosis, osteoporose

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The main study parameter is the difference in change of serum concentrations of bone turnover markers (procollagen type I N propeptide (P1NP) and C-terminal crosslinking telopeptides of collagen type I (CTX)) compared in the treatment and control groups.

Secondary outcome

A secondary parameter is the change in number of circulating stem cells and osteogenic cells.

Study description

Background summary

Rationale:

Osteoporosis is a common disease, characterized by low bone mass and skeletal fragility resulting in an increased risk of fracture. The most prevalent cause of osteoporosis is estrogen deficiency in postmenopausal women. Estrogen replacement therapy and bisphosphonates effectively reduce fracture risk, but there are concerns about the long-term safety of these treatments. Bone mass is controlled by the balance between bone formation and resorption. The anabolic effects of estrogen on bone are presumed to be mediated by the estrogen receptor in bone. However, a recent breakthrough in experimental animals indicates an important role for the sympathetic nervous system (SNS) in bone remodelling mediated by the beta-2-adrenergic receptor. Furthermore, there are reports that the SNS is involved in the mobilization of hematopoietic stem cells.

Objective:

The objective is to study the effect of beta-agonist and beta-antagonist treatment on human bone remodeling.

Study design:

Randomized intervention trial.

Study population:

Female postmenopausal volunteers.

Intervention:

The participants will be randomized to receive hormonal replacement therapy (HRT)

(estradiol/dydrogeston 1dd 1/10 mg), HRT and beta-agonist (salbutamol 1dd 4 mg), beta-antagonist (propranolol SR 1dd 80 mg) or no treatment during twelve weeks.

Main study parameters/endpoints:

The main study parameter is the difference in change of serum concentrations of bone turnover markers (procollagen type I N propeptide (P1NP) and C-terminal crosslinking telopeptides of collagen type I (CTX)) compared in the treatment and control groups(6). A secondary parameter is the change in number of circulating stem cells and osteogenic cells.

Study objective

The hypothesis is that estrogen has a central effect on bone remodeling through the sympathetic nervous system.

Study design

1. Baseline;

2. 4 weeks;

3. 8 weeks;

4. 12 weeks.

Intervention

The participants will be randomized to receive hormonal replacement therapy (HRT) (estradiol/dydrogeston 1dd 1/10 mg), HRT and beta-agonist (salbutamol 1dd 4 mg), beta-antagonist (propranolol SR 1dd 80 mg) or no treatment during twelve weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Female sex;

2. Last menstrual cycle 12-60 months ago.

Exclusion criteria

1. Contraindications to HRT, beta-agonist or beta-antagonist treatment, such as cardiovascular disease, astma, COPD, renal or hepatic insufficiency;

2. Any medication or disease influencing bone turnover;

3. Prior VTE or breast cancer;

4. Current osteoporosis defined by a DXA T-score >-2.5.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-05-2011
Enrollment:	32
Type:	Actual

Ethics review

Positive opinion
Date: 29-04-2011
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36023
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2736
NTR-old	NTR2874
CCMO	NL35737.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36023

Study results

Summary results
N/A