The nervous system, estrogen and osteoporosis.

Gepubliceerd: 29-04-2011 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25589

Bron
Nationaal Trial Register

Verkorte titel
E2Bone

Aandoening

osteoporosis, osteoporose

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

1. Baseline;

2. 4 weeks;

3. 8 weeks;

4. 12 weeks.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female sex;

2. Last menstrual cycle 12-60 months ago.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	32
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-04-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36023
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A