Bone, testosterone and glucose metabolism.

Gepubliceerd: 14-02-2013 Laatst bijgewerkt: 19-03-2025

The hypothesis is that bone influences the male gondal axis and insuline sensitivity.

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

Samenvatting

ID

NL-OMON27144

Bron
NTR

Verkorte titel
HGB-study

Aandoening

Osteoporosis

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) Amsterdam
Overige ondersteuning: Academic Medical Center (AMC) Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Undercarboxylated osteocalcin;
2. Testosterone concentrations;
3. Glucose tolerance determined by an oral glucose tolerance test;

4. Insulin sensitivity determined by a hyperinsulinemic euglycemic clamp.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Osteoporosis is a common disease that is characterized by low bone mass with microarchitectural disruption and skeletal fragility, resulting in increased risk of fracture. Normally, bone quality is maintained by a dynamic process, known as bone remodeling. Animal research shows that osteocalcin, secreted by osteoblasts, acts as a hormone and influences the male gonal axis and insuline sensitivity.

Objective of the study:

The objective of the study is to study the relationship between undercarboxylated osteocalcin levels, testosterone concentrations, glucose tolerance and insulin sensitivity in male subjects with primary osteoporosis.

Study design:

Open label randomized controlled cross-over trial.

Study population:

Male objects with recently diagnosed primary osteoporosis.

Intervention:

The participants will be randomized to two treatment groups (Teriparatide 12 weeks or no treatment 12 weeks), in a cross-over design.

Main study parameters/endpoints:

1. Undercarboxylated osteocalcin;

2. Testosterone concentrations;

3. Glucose tolerance;

4. Insulin sensitivity.

Doel van het onderzoek

The hypothesis is that bone influences the male gondal axis and insuline sensitivity.

Onderzoeksopzet

Baseline, 6 weeks, 12 weeks, 18 weeks, 24 weeks.

Onderzoeksproduct en/of interventie

The participants will receive Teriparatide treatment for 12 weeks and no treatment for 12 weeks in a crossover design.

After finishing both interventions (t=12 weeks and t=24 weeks) patients will undergo an oral glucose tolerance test and a hyperinsulinemic euglycemic clamp, and whole body dual-energy X-ray absorptiometry (DXA scan).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male sex 50-80 years;

2. Recently diagnosed primary osteoporosis (T-score between -2.5 and -3.5);

3. Testosterone within reference range.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Contraindication to parathyroid hormone therapy: hypersensitivity to the active substrate or to any of the excipients, pre-existing hypercalcaemia, hepatic- or renal insufficiency, metabolic bone diseases other than primary osteoporosis or glucocorticoid-induced osteoporosis, unexplained elevations of alkaline phosphatase, prior external beam or implant radiation therapy to the skeleton, patients with skeletal malignancies or bone metastases;

2. Any medication or disease influencing bone turnover;

3. Diabetes mellitus;

4. Hypogonadism;

5. Inability to give informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2013
Aantal proefpersonen:	8
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41473
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3689
NTR-old	NTR3859
CCMO	NL42624.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41473

Resultaten

Samenvatting resultaten
NA