Cholecalciferol in elderly with osteoarthritis of the hip.

Gepubliceerd: 17-07-2009 Laatst bijgewerkt: 18-08-2022

It is hypothesised that a loading dose of 150,000 IU cholecalciferol and of 300,000 IU are both effective in normalizing serum 25-OHD in insufficient en deficient individuals, but also in elevating serum 25-OHD in elderly with sufficient serum 25-...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27613

Bron
NTR

Verkorte titel
Cholecalciferol in elderly with osteoarthritis of the hip

Aandoening

vitamin D, deficiency, total hip, cholecalciferol, osteoarthritis

Ondersteuning

Primaire sponsor: RdGG hospital
Overige ondersteuning: fund= initiator = sponsor= RdGG hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine the effect of 150,000 vs 300,000 IU cholecalciferol on serum 25-OHD on day 3, 5, 14 and after 6 weeks and 3 months in patients undergoing major orthopaedic surgery or

receiving conservative treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Vitamin D insufficiency and deficiency are becoming a worldwide problem. It is associated with increased risk of falling, osteoporosis and increased risk of fractures. Elderly are more at risk for vitamin D insufficiency and deficiency. Several strategies for vitamin D suppletion are used, however a high loading dose is hardly used.

Objective:
To study the effect of high dose oral cholecalciferol suppletion on serum 25-OHD in elderly with coxarthrosis.

Study design:
A randomised double-blinded controlled clinical trial.

Study population:
Patients with coxarthrosis aged 70 years and older.

Intervention (if applicable):
Two groups of patients will be formed, one group of patients being treated conservative, one group of patients who will be operated. Within both groups the patients will be randomised between getting a single oral dose of either 150,000 IU or 300,000 IU cholecalciferol.

Main study parameters/endpoints:
The effect of different doses cholecalciferol on serum 25-OHD.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

A high loading dose is a potent way of raising serum 25-OHD. In theory, there is a risk of vitamin D toxicity. Extra blood test form an additional burden as well as extra visits to the clinic.

Doel van het onderzoek

It is hypothesised that a loading dose of 150,000 IU cholecalciferol and of 300,000 IU are both effective in normalizing serum 25-OHD in insufficient en deficient individuals, but also in elevating serum 25-OHD in elderly with sufficient serum 25-OHD without toxicity, meaning that the lowest of both doses is preferred. It is not expected that elective hip surgery will influence cholecalciferol uptake.

Onderzoeksopzet

On day 3, 5, 14 and after 6 weeks and 3 months.

Onderzoeksproduct en/of interventie

150,000 or 300,000 IU cholecalciferol.

Contactpersonen

Publiek

Dept internal medicine RdGG Delft
J. Alsma
Dept internal medicine RdGG Delft
Delft
The Netherlands
+31 15 2603257

Wetenschappelijk

Dept internal medicine RdGG Delft
J. Alsma
Dept internal medicine RdGG Delft
Delft
The Netherlands
+31 15 2603257

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Informed consent signed by patient;

2. Male and female patients aged 70 years and older;

3. If female: of non child bearing potential;

4. Diagnoses of osteoarthritis of the hip;

5. Baseline level of serum 25-OHD <100 nmol/liter;

6. For inclusion in the conservative treatment group: Patients having coxarthrosis, which will be treated conservative;

7. For inclusion in the operative group: Patients having disabling coxarthrosis and scheduled for elective total hip surgery.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Unwillingness to cooperate with the study procedures;

2. History of an active malignancy;

3. Quetelet index (QI=weight in (kilogram)/ squire length (meters)) >40;

4. History of chronic kidney disease (glomerular filtration rate (GFR) <20ml/min, calculated with Cockcroft-Gault equations);

5. History of primary hyperparathyroidism;

6. History of sarcoidosis;

7. Serum calcium corrected for serum albumin above 2.65nmol/l.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland
Status: Werving nog niet gestart

(Verwachte) startdatum:	01-11-2009
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1805
NTR-old	NTR1915
Ander register	: 26165
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A