The effect of high dose cholecalciferol orally on serum of vitamin D in elderly with osteoarthritis of the hip

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To study the effect of high dose oral cholecalciferol suppletion on serum 25-OHD in elderly with osteoarthritis of the hip.

Ethical review	Not approved
Status	Will not start
Health condition type	Bone, calcium, magnesium and phosphorus metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON37463

Source
ToetsingOnline

Brief title
cholecalciferol in elderly with osteoarthritis of the hip

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders

Synonym
Vitamin D deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Ministerie van OC&W,Wetenschappelijke Activiteiten Commissie (WAC) Reinier de Graaf Groep

Intervention

Keyword: cholecalciferol, osteoarthritis of the hip, vitamin D3

Outcome measures

Primary outcome

The effect of different doses cholecalciferol on serum 25-OHD

Secondary outcome

- To determine the effect of 150,000 vs 300,000 IU cholecalciferol on serum calcium and PTH on day 3, 5, 14 and after 6 weeks and 3 months

- To determine the effect of surgery on the absorption of cholecalciferol

- To determine the effect of surgery on serum calcium and PTH

- To determine whether there is a wash-out period of the effect of cholecalciferol during 3 months of follow up, i.e. what is the time serum 25-OHD is remains above 50nmol/liter after a single oral dose of cholecalciferol.

- To determine changes in general well being measured by SF-12.

- To determine whether there is relapse of patients from sufficient to insufficient or deficient

Study description

Background summary

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.

Study objective

To study the effect of high dose oral cholecalciferol suppletion on serum 25-OHD in elderly with osteoarthritis of the hip.

Study design

A randomised double-blinded controlled clinical trial.

Intervention

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

Study burden and risks

A high loading dose is a potent way of raising serum 25-OHD. In theory, there is a risk of vitamin D toxicity resulting in hypercalcaemia. Patients can be allergic to one of the ingredients of cholecalciferol. Extra blood test form an additional burden as well as extra visits to the clinic and filling in the SF-12 forms.

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

1. Informed consent signed by patient;2. Male and female patients aged 70 years and older;3. Diagnoses of osteoarthritis of the hip.;4. Baseline level of serum 25-OHD <100 nmol/liter ;5. For inclusion in the conservative treatment group: Patients having osteoarthritis of the hip, which will be treated conservative.;6. For inclusion in the operative group: Patients having disabling osteoarthritis of the hip and scheduled for elective total hip surgery.

Exclusion criteria

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

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	cholecalciferol 50.000 IU/ml
Generic name:	cholecalciferol 50.000 IU/ml

Ethics review

Approved WMO

Date:	06-08-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Not approved

Date:	09-10-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-000040-10-NL
CCMO	NL39393.098.12