Cholecalciferol in elderly with osteoarthritis of the hip.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27613

Source
NTR

Brief title
Cholecalciferol in elderly with osteoarthritis of the hip

Health condition

vitamin D, deficiency, total hip, cholecalciferol, osteoarthritis

Sponsors and support

Primary sponsor: RdGG hospital
Source(s) of monetary or material Support: fund= initiator = sponsor= RdGG hospital

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. 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;

2. To determine the effect of surgery on the absorption of cholecalciferol;

3. To determine the effect of surgery on serum calcium and PTH;

4. 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;

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

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

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

150,000 or 300,000 IU cholecalciferol.

Contacts

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Eligibility criteria

Inclusion criteria

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.

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 type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2009
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1805
NTR-old	NTR1915
Other	: 26165
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A