

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

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Bone, calcium, magnesium and phosphorus metabolism disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32592

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

## 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

A pilot 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 pilot 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

### Public

Reinier de Graaf Groep

reinier de graafweg 3-11  
2625 AD Delft  
Nederland

### Scientific

Reinier de Graaf Groep

reinier de graafweg 3-11  
2625 AD Delft  
Nederland

## 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)/ square 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:	2
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:	09-04-2010
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	EUCTR2009-011301-16-NL
CCMO	NL30202.098.09