

# Vitamin D suppletion and aspecific musculo-skeletal disorders

Published: 11-01-2008

Last updated: 11-05-2024

To investigate the effect of suppletion of vitamin D on aspecific musculo-skeletal disorders

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Muscle disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33615

### Source

ToetsingOnline

### Brief title

-

### Condition

- Muscle disorders

### Synonym

musculo-skeletal disorders, widespread pain

### Research involving

Human

### Sponsors and support

**Primary sponsor:** F. Schreuder

**Source(s) of monetary or material Support:** door onderzoeker zelf

### Intervention

**Keyword:** musculo-skeletal disorders, vitamin D

## Outcome measures

### Primary outcome

difference in complaints between inclusion date and 6 weeks after 150.000 IU

cholecalciferol or 300.000 IU

### Secondary outcome

difference in complaints between inclusion date and 12 weeks after 150.000 IU

cholecalciferol (or placebo)

difference in improvement in localisation of complaints

vit D level on inclusion

vit D level at 12 weeks

difference in vit D levels wee12 and on inclusion with 150.000 or 300.000 IU

## Study description

### Background summary

Vitamin D deficiency is common in Asian and African immigrants and their offspring.

Also are musculo-skeletal disorders.

Several case-reports are published about a healing effect of vitamin D suppletion as a therapy for this disorders and also some observational studies suggest this, while others could not find an effect.

No RCT was found in scientific litterature on this subject, though an effect on muscle strenght seems to be proven and is suggested in the elderly.

### Study objective

To investigate the effect of suppletion of vitamin D on aspecific musculo-skeletal disorders

### Study design

Double blinded cross-over RCT

### **Intervention**

1 or 2 times 150.000 IU cholecalciferol

### **Study burden and risks**

Burdon patient: possibility of 6 weeks postponement of treatment for long lasting complaints

1 extra venapunction

1 extra consult

3 extra registration of complaints (4 questions)

Risk patient: No risk

## **Contacts**

### **Public**

F. Schreuder

Handellaan 108  
2625 SN Delft  
NL

### **Scientific**

F. Schreuder

Handellaan 108  
2625 SN Delft  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)  
Elderly (65 years and older)

## Inclusion criteria

asian or african origin  
18-60 yrs  
> 6wk complaininig of muscle-pain or weakness

## Exclusion criteria

Specific diseases causing musclepain like polymyalgia rheumatica, arthritis (depression or fibromyalgia or somatisationdisorder are no exclusion-criteria)  
use of statines or ciclosporine  
use of vit D suppletion in the past 4 months  
ESR > 30, Kreat > 150 mmol/L  
sarcoidose, TBC

## Study design

### Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2008
Enrollment:	82
Type:	Actual

## Medical products/devices used

Product type:	Medicine
Brand name:	-
Generic name:	cholecalciferol
Registration:	Yes - NL intended use

## Ethics review

Approved WMO	
Date:	11-01-2008
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	EUCTR2007-001483-79-NL
Other	ISRCTN 54027991
CCMO	NL17530.098.07