Effect of cholecalciferol on the systolic blood pressure in hypertensive, vitamine D insufficient patients.

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To evaluate the effect of cholecalciferol supplection on the systolic blood pressure in hypertensive patients with a 25-hydroxycholecalciferol insufficiency. Secondly, the effects on PRA, aldosteron, 25-hydroxycholecalciferol, alkaline phosphatase,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vitamin related disorders
Study type	Interventional

Summary

ID

NL-OMON39286

Source
ToetsingOnline

Brief title
Vitamin-D-bloodpressure-effect in Vit D-insufficient+hypertensive patients

Condition

- Vitamin related disorders

Synonym
high blood pressure, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Bronovo Ziekenhuis
Source(s) of monetary or material Support: Research Fonds Bronovo

Intervention

Keyword: cholecalciferol, hypertension, systolic blood pressure, vitamin D insufficiency

Outcome measures

Primary outcome

systolic blood pressure

Secondary outcome

Plasma renin activity

Aldosteron

25-hydroxycholecalciferol

Alkaline phosphatase

Parathyroid hormone

the need of adjusting the antihypertensive therapy

anti-inflammatoire activity of vitamin D

Study description

Background summary

Vitamin D insufficiency is common because of lack of sunshine exposure and too little availability of vitamin-D-rich foodsources. Low vitamin D concentrations are associated with an increased risk of hypertension, diabetes and cardiovascular diseases, such as myocardial infarction. Suppletion of vitamin D reduces the all-cause mortality in especially the elderly. Research in the relation of low vitamin D concentrations and hypertension shows that:
- the prevalence of hypertension increases when distance to the equator increases
- in winter measured blood pressures are higher
- relative risk to hypertension increases strongly with 25-hydroxycholecalciferol concentrations below 37,5 nmol/l
- in the vitamin D insufficient, hypertensive elderly suppletion of the combination of calcium and vitamine D shows larger decreases in systolic blood pressure and PTH than suppletion of calcium alone.

- the plasma renin activity (PRA) increases with decreasing vitamin D concentrations
There is research done to confirm the anti-inflammatoire activity of vitamin D in vitro by the CHDR in Leiden. In this research the anti-inflammatoire activity of vitamin D in vivo will be investigated.

Study objective

To evaluate the effect of cholecalciferol supplection on the systolic blood pressure in hypertensive patients with a 25-hydroxycholecalciferol insufficiency. Secondly, the effects on PRA, aldosteron, 25-hydroxycholecalciferol, alkaline phosphatase, PTH and the effect on the need of adjusting the antihypertensive therapy are evaluated. Evaluation if the anti-inflammatoire activity of vitamin D in vivo can be confirmed.

Study design

double blind, randomised, placebo-controlled intervention study.

Intervention

group 1 takes 2 tablets of cholecalciferol 1000 IE each day for 12 months.
group 2 takes 2 placebo tablets each day for 12 months.
The placebo tablets are manufactured by the Central Hospital Pharmacy, The Hague.

Study burden and risks

The extra load consists of 1 extra visit to the policlinic (including blood pressure control, blood and urine sampling) and 2 times a 24-hrs bloodpressure monitoring (+1x optional). In addition the subject needs to take 2 extra tablets daily for 12 months.

The risk of adverse events with this dose of cholecalciferol and with the low concentration of 25-hydroxycholecalciferol at the time of inclusion is very low. The only known adverse event, which usually occurs only after taking high daily doses chronically (> 10.000 IE per day) is hypercalcemia. By determining the calciumconcentrations in blood every 6 months, we expect to recognize this adverse event in an early stage. In addition all subjects are warned for the adverse event and how to recognize it in an early stage (by: feeling of weakness, fatigue, headage, dry mouth, nausea, vomiting, diarrhea, obstipation, dizziness, disturbance of movement coordination, muscle- and bonepain, itch and cardiac palpitation).

The extra load is considered to be mediocre, the risks to be minimal.

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

- the patient has signed an informed consent
- the patient is an adult male or female (age 18 yr or above)
- the patient is diagnosed with a systolic hypertension (> 140 mmHg), measured in Bronovo Hospital between t=-12 months and t=0 months
- the patient is vitamin D insufficient, defined as having a 25-hydroxycholecalciferol concentration between 20-50 nmol/l measured in Bronovo Hospital between t=-12 months and t=0 months

Exclusion criteria

- using prescribed cholecalciferol supplement (>= 400 IE/day) after t = -2 months

- MDRD below normal for age/gender
- for albumin corrected serum calcium > 2,60 mmol/L
- existing malignancy which is treated.
- disease of Besnier-Boeck (sarcoidosis)
- pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2010
Enrollment:	110
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	PLACEBO Cholecalciferol 1000 IE tablet
Generic name:	PLACEBO Cholecalciferol 1000 IE tablet
Product type:	Medicine
Brand name:	Vigantoletten 1000 IE tablet
Generic name:	Cholecalciferol 1000 IE tablet
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	13-02-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-04-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-06-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-09-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-02-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-03-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	04-05-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	21-02-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	27-02-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO Date:	11-07-2013
Application type:	Amendment
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

ID: 20826
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2009-009600-39-NL
CCMO	NL26675.098.09
OMON	NL-OMON20826

Study results

Date completed:	18-12-2014
Actual enrolment:	109