Effect of vitamin D on the systolic blood pressure in hypertensive patients with low vitamine D levels.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20826

Source
NTR

Brief title
N/A

Health condition

systolic hypertension, vitamin D insufficiency.
systole hypertensie, vitamine D insufficientie.

Sponsors and support

Primary sponsor: Dr. Y.W.J. Sijpkens, internist-nephrologist
Drs. W.J. Liefers, hospital pharmacist in training.
Source(s) of monetary or material Support: The Bronovo Research Fund.

http://www.bronovo.nl/Bronovo/en-GB/bronovo/about_bronovo/research_fund/

Intervention

Outcome measures

Primary outcome

Systolic blood pressure.

Secondary outcome

1. Plasma renin concentration;

2. Aldosteron;

3. 25-hydroxycholecalciferol;

4. Alkaline phosphatase;

5. Parathyroid hormone;

6. The need of adjusting the antihypertensive therapy.

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 relation to low vitamin D concentrations and hypertension shows that:

1. The prevalence of hypertension increases when distance to the equator increases;

2. In winter measured blood pressures are higher;

3. Relative risk to hypertension increases strongly with 25-hydroxycholecalciferol concentrations below 37,5
nmol/l;

4. 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;

5. The plasma renin activity (PRA) increases with decreasing vitamin D concentrations.

In this double blind, randomised, placebo-controlled intervention study we want to evaluate the effect of cholecalciferol supplection on the systolic blood pressure in hypertensive patients
with a 25-hydroxycholecalciferol insufficiency. Secondly, the effects on PRC, aldosteron, 25-hydroxycholecalciferol, alkaline phosphatase, PTH and the effect on the need of adjusting the antihypertensive therapy are evaluated.

Only policlinical patients from Hospital Bronovo in The Hague, the Netherlands, can be included.

Study objective

Does suppletion of vitamine D3 (cholecalciferol) have an effect on the systolic blood pressure in hypertensive, vitamin D insufficient patients?

1. H0 hypothesis: there is no effect on the systolic blood pressure;

2. H1 hypothesis: the systolic blood pressure decreases with at least 5 mm Hg.

Study design

1. T = 0, 6, 12 months:

A. Blood pressure;

B. Albumin;

C. For albumin corrected serum calcium;

D. Phosphate;

E. Plasma renin concentration;

F. Aldosteron;

G. 25-OH-Vitamin D;

H. 1,25-(OH)2-Vitamin D;

I. Parathyroid hormone (PTH);

J. Uric acid;

K. Alkaline phosphatase;

L. Fasting insulin;

M. Fasting glucose;

N. HbA1c;

O. CRP;

P. HsCRP;

Q. Creatinine/eGFR (MDRD);

R. Hemocytometry;

S. Triglycerides;

T. Cholesterol;

U. LDL-cholesterol;

V. FGF23 Calcium creatinine ratio in urine;

W. FGF23;

X. Calcium creatinine ratio in urine;

Y. Sodium creatinine ratio in urine;

Z. Abumin creatinine ratio in urine;

AA. Urine phosphate.
2. T = 0, 12 months:

A. 24-hr blood pressure (optional at T = 6 months).

Intervention

1. Group 1: 2 oral tablets of cholecalciferol 1000 IE (= 50 microg) each day for 12 months;

2. Group 2: 2 placebo oral tablets each day for 12 months.

Placebo tablets are manufactured by the Central Hospital Pharmacy, The Hague.

Contacts

Public
-
W.J. Liefers
Montessoriweg 1

Rotterdam 3083 AN
The Netherlands
+31 (0)10-2975959
Scientific
-
W.J. Liefers
Montessoriweg 1

Rotterdam 3083 AN
The Netherlands
+31 (0)10-2975959

Eligibility criteria

Inclusion criteria

1. The patient has signed an informed consent;

2. The patient is an adult male or female (age 18 yr or above);

3. The patient is diagnosed with a systolic hypertension (> 140 mmHg);

4. The patient is vitamin D insufficient, defined as having a 25-hydroxycholecalciferol concentration between 20-50 nmol/l.

Exclusion criteria

1. Using prescribed cholecalciferol supplement (equal to or more than 400 IE = 10 microg/day) after t = -2 months;

2. MDRD below normal for age/gender;

3. for albumin corrected serum calcium equal to or above 2,60 mmol/L;

4. Existing malignancy which is being treated;

5. Disease of Besnier-Boeck (sarcoidosis);

6. Pregnancy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-04-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39286
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1676
NTR-old	NTR1777
CCMO	NL26675.098.09
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON39286

Study results

Summary results
N/A