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

Gepubliceerd: 25-04-2009 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20826

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: Dr. Y.W.J. Sijpkens, internist-nephrologist
Drs. W.J. Liefers, hospital pharmacist in training.
Overige ondersteuning: The Bronovo Research Fund.

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Systolic blood pressure.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

-
W.J. Liefers
Montessoriweg 1

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

Wetenschappelijk

-
W.J. Liefers
Montessoriweg 1

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2009
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-04-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39286
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A