

Does vitamin D reduce blood pressure and left ventricular (LV) mass in resistant hypertensive patients with vitamin D insufficiency?

Submission date 28/03/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/04/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/11/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

People who have high blood pressure despite taking three or more blood pressure lowering medications have a condition called resistant hypertension. This group of patients struggle to find medications that reduce their blood pressure effectively, and thus remain at higher risk of future heart attack and stroke. Persistently high blood pressure also leads to thickening of the heart muscle, which can lead to impaired heart function and rhythm disturbances. Vitamin D levels are low in many people in Scotland, and low vitamin D levels have been found to be associated with higher blood pressure. The aim of this study is to test whether vitamin D supplements could improve blood pressure and reverse the thickening of the heart muscle that is common in people with resistant hypertension.

Who can participate?

Men and women aged over 18 with resistant hypertension

What does the study involve?

Participants are randomly allocated to receive either a large dose of vitamin D every 2 months, or a dummy (placebo) dose. At the beginning of the study, blood pressure is measured at rest and over 24 hours. Heart muscle thickness is measured using MRI scans in those patients with a thickened heart muscle. The MRI scans are repeated after 6 months, and measured blood pressure at 2, 4 and 6 months.

What are the possible benefits and risks of participating?

The benefit of taking part is that a new way of treating difficult-to-treat high blood pressure might be found. The risks are very small as vitamin D is very safe. It can very rarely increase the risk of kidney stones, although whether it really does this or not is controversial.

Where is the study run from?

Ninewells Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2008 to May 2013

Who is funding the study?
Chest Heart and Stroke Scotland (UK)

Who is the main contact?
Prof. Allan Struthers
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2008-002681-63

Protocol serial number
Res08/A115

Study information

Scientific Title
Does vitamin D reduce blood pressure and left ventricular (LV) mass in resistant hypertensive patients with vitamin D insufficiency? A double-blind, placebo-controlled, parallel-group randomised trial

Study objectives
That vitamin D supplementation in patients with resistant hypertension and insufficient vitamin D levels will lead to clinically important reductions in blood pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Study design

Double-blind placebo-controlled parallel-group randomised trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hypertension

Interventions

100,000 units of oral vitamin D3 every two months or placebo.

Total treatment duration: 4 months

Total follow up: 6 months

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Vitamin D supplementation

Primary outcome(s)

Office BP, measured at 0, 2, 4 and 6 months

Key secondary outcome(s)

LV mass index, measured by cardiac magnetic resonance imaging [MRI] at 0 and 6 months

Completion date

01/05/2013

Eligibility

Key inclusion criteria

1. Aged greater than 18 years, either sex
2. Serum 25-hydroxy vitamin D less than 75 nmol/L
3. Office blood pressure (BP) greater than 140/90 mmHg despite three or more anti-hypertensives

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Hypertension known to be due to a correctable underlying medical or surgical cause
2. Estimated glomerular filtration rate less than 40 ml/min (by four variable Modification of Diet in Renal Disease [MDRD] equations)
3. Liver function tests (alanine aminotransferase [ALT], bilirubin, alkaline phosphatase) greater than 3 x normal
4. Corrected calcium greater than 2.60 mmol/L or less than 2.15 mmol/L
5. Known metastatic malignancy or sarcoidosis
6. Clinical diagnosis of osteomalacia
7. History of renal calculi
8. Diagnosis of heart failure with left ventricular systolic dysfunction
9. Atrial fibrillation
10. Already taking vitamin D supplements. Consumption of fish oils will not be a contra-indication to enrolment
11. Unable to give written informed consent
12. Pregnant or of childbearing age and not taking reliable contraception

Date of first enrolment

01/01/2009

Date of final enrolment

01/08/2011

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre

Ninewells Hospital

Dundee

United Kingdom

DD1 9SY

Sponsor information

Organisation

University of Dundee

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Charity

Funder Name

Chest Heart and Stroke Scotland

Alternative Name(s)

Chest Heart & Stroke Scotland, CHSScotland, CHSS

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Catrina Forde (c.forde@dundee.ac.uk). Study data are available for non-commercial, bona-fide academic analyses in collaboration with the authors; decisions on data access will be made between the investigators and the Sponsor (University of Dundee).

Participant consent for unrestricted sharing of individual participant data was not obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No

[Basic results](#)

06/11/2017

07/11/2017

No

No