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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

Registration date
21/04/2008

Overall study status
Completed

Last Edited
07/11/2017

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number
2008-002681-63

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)
Ethics Board of Fife, Forth Valley and Tayside Research Ethics Service, 06/08/2008, ref: 08/S1402/31

Study design
Double-blind placebo-controlled parallel-group randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

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

Overall study start date
01/03/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
74

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
Scotland

United Kingdom

Study participating centre
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee

Sponsor details
Research and Innovation Services
11 Perth Road
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United Kingdom
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Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
Chest Heart and Stroke Scotland

Alternative Name(s)
Chest Heart & Stroke Scotland, CHSS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol is available from the authors on request but is not available online.

Intention to publish date

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