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Vitamin D for Isolated Systolic Hypertension (VitDISH)

Submission date	Recruitment status	[X] Prospectively registered
01/07/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/08/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/11/2017	Circulatory System	

Plain English summary of protocol

Background and study aims
Small studies have shown that vitamin D, a hormone that the skin usually makes using sunshine, may be able to reduce blood pressure in some people. The majority of people in Scotland have low levels of vitamin D, and people with low vitamin D tend to have higher blood pressure. People with high blood pressure have blood vessels that do not work as well as normal, and this leads to a higher risk of heart problems and strokes. The aim of this study is therefore to test whether giving extra vitamin D every three months to people with high blood pressure and low vitamin D levels helps to reduce blood pressure and other measures of blood vessel and heart health.

Who can participate?
Patients aged 70 and over with high blood pressure and low vitamin D levels

What does the study involve?
Participants are randomly allocated to be given either a teaspoon of vitamin D oil or a placebo (dummy) oil once every 3 months for 12 months. Participants visit the hospital at the start of the study and after 3, 6, 9 and 12 months. Each visit lasts two hours. These visits involve measuring blood pressure, taking blood samples, testing the arteries, a walking test, and answering questionnaires. After each visit, participants are given a teaspoon of the vitamin D or placebo oil to swallow. They are asked to keep a diary of any falls they have between now and the next visit.

What are the possible benefits and risks of participating?
Although participants are unlikely to benefit directly by taking part in the study, those who receive the vitamin D might find that their blood pressure is lower. Although this dose of vitamin D has been used before and is known to be safe there is a small possibility of side effects. Participants are closely monitored for side effects caused by high calcium levels: sickness, diarrhoea, thirst or dizziness. To reduce the chance of vitamin D increasing the blood calcium level, participants are asked to not take vitamin D or calcium supplements while they are taking part in this study. Having blood taken can cause some bruising. The blood pressure cuff causes mild discomfort to some people.

Where is the study run from?
Ninewells Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2009 to January 2012

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Dr Miles Witham
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2007CV09

Study information

Scientific Title
Can high-dose vitamin D supplementation reduce blood pressure and markers of cardiovascular risk in older people with isolated systolic hypertension? A randomised, double-blind, parallel group placebo controlled trial

Acronym
VitDISH

Study objectives
That supplementation with 100,000 units of vitamin D3 every 3 months will produce reductions in blood pressure and improvements in markers of vascular health in patients aged greater than 70 years with isolated systolic hypertension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fife and Forth Valley Research Ethics Committee, 15/12/2008, ref: 08/S0501/90

Study design
Randomised double-blind parallel-group placebo-controlled 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
Isolated systolic hypertension

Interventions
100,000 units of vitamin D3 or placebo every 3 months for 1 year.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin D supplementation

Primary outcome measure
Change in office blood pressure at 3 months

Secondary outcome measures

1. Change in office blood pressure at 0, 6, 9, 12 months
2. Change in 24 hour mean blood pressure at 0, 3, 6, 9, 12 months
3. Change in B-type natriuretic peptide, high sensitivity C-reactive protein (hsCRP) and homeostatic model assessment (HOMA) index at 0, 3 and 12 months
4. Change in endothelial function measured by flow-mediated dilatation of the brachial artery (FMD) at 0, 3 and 12 months
5. Change in pulse wave velocity at 0, 3 and 12 months
6. Change in 25-hydroxy vitamin D and parathyroid hormome (PTH) levels, cholesterol and triglycerides

Overall study start date
09/10/2008

Completion date
31/07/2012

Eligibility

Key inclusion criteria
1. Aged greater than or equal to 70 years, either sex
2. Office systolic blood pressure (BP) greater than 140 mmHg
3. Serum 25 hydroxy vitamin D less than 75 nmol/L

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Hypertension known to be due to a correctable underlying medical or surgical cause
2. Diastolic blood pressure greater than 90 mmHg
3. Systolic blood pressure greater than 180 mmHg
4. Estimated glomerular filtration rate less than 40 ml/min (by four-variable modification of diet in renal disease rate [MDRD] equation)
5. Liver function tests (alanine aminotransferase [ALT], bilirubin, alkaline phosphatase) greater than 3 x normal
6. Corrected calcium greater than 2.60 mmol/L or less than 2.15 mmol/L
7. Known metastatic malignancy or sarcoidosis
8. Clinical diagnosis of osteomalacia
9. History of renal calculi
10. Diagnosis of heart failure with left ventricular systolic dysfunction
11. Atrial fibrillation

12. Already taking vitamin D supplements (consumption of fish oils will not be a contraindication to enrolment)
13. Unable to give written informed consent

Date of first enrolment
01/02/2009

Date of final enrolment
31/01/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ninewells Hospital
Dundee
United Kingdom
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Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Research and Innovation Services
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Sponsor type
University/education

Website
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ROR

https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (ref: CZH/4/470)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

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	14/10/2013		Yes	No
Basic results		01/11/2017	07/11/2017	No	No
HRA research summary			28/06/2023	No	No