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Does vitamin D improve markers of vascular health in stroke patients?

Submission date 21/02/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 01/05/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 26/02/2018	**Condition category** Circulatory System	[_] Individual participant data

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 and improve blood vessel health in some people. People who have had a stroke very often have low vitamin D levels, 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 the study is therefore to test whether giving extra vitamin D to people who have had a stroke in the past helps to reduce blood pressure and improve other measures of blood vessel and heart health.

Who can participate?
Adults aged 18 years and over who have had a stroke

What does the study involve?
The study lasts for 16 weeks. Participants are randomly allocated to one of two groups, and given either a single capsule of vitamin D or a matching placebo (dummy) tablet.
Participants are assessed at the start, and 8 weeks and 16 weeks, with each visit lasting 1.5 hours. At each visit, participants receive some or all of the following depending on which visit it is:
- Blood pressure measured
- Blood sample taken
- Test the function of the artery in their arm. The artery is scanned with an ultrasound machine before and after inflating a blood pressure cuff on their forearm for 5 minutes. The test is repeated after giving the participant a medication (GTN) spray under their tongue.
- Wear a blood pressure cuff and a heart rate monitor (ECG) for 24 hours including at home

What are the possible benefits and risks of participating?
Although participants are unlikely to benefit directly by taking part in the trial, those who receive the vitamin D might find that 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 calcium level in their blood, participants are also asked not to take vitamin D

supplements or calcium supplements whilst 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 Dundee (UK)

When is the study starting and how long is it expected to run for?
September 2006 to May 2009

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

Who is the main contact?
Dr Miles Witham (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Res/A107

Study information

Scientific Title

The effect of vitamin D replacement on markers of vascular health in stroke patients - a randomised controlled trial

Study objectives
That a single dose of oral vitamin D can lower blood pressure and improve endothelial function in stroke patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Local Research Ethics Committee,14/05/200, ref: 07/S1401/41

Study design
Double blind randomised 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
A single oral dose of 100,000 U ergocalciferol (vitamin D) or placebo.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Blood pressure (seated office and 24 hour measurements) (added 26/02/2018: measured using a blood pressure cuff) at baseline, 8 and 16 weeks after vitamin D administration.

Secondary outcome measures

Current secondary outcome measures (as of 26/02/2018):
All outcomes are measured at baseline, and 8 and 16 weeks after vitamin D administration:
1. Endothelial function of the artery in the arm is measured using ultrasound following an inflated blood pressure cuff
2. B-type natriuretic peptide is measured from a blood sample
3. Heart rate variability is measured using a 24 hour ECG
4. Vitamin D deficiency is measured using 25OHD

Previous secondary outcome measures;
The secondary outcomes will also be measured at baseline and then at 8 and 16 weeks after vitamin D administration.

1. Endothelial function
2. B-type natriuretic peptide
3. Heart rate variability

Overall study start date
30/09/2006

Completion date
31/05/2009

Eligibility

Key inclusion criteria
1. Clinical diagnosis of completed stroke (ischaemic or haemorrhagic)
2. Serum 25-hydroxy vitamin D level less than 50 nmol/L

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
68 (two groups of 34)

Key exclusion criteria
1. Hyper- or hypocalcaemia
2. Metastatic malignancy
3. Liver function tests over three times limit of normal
4. Estimated glomerular filtration rate (GFR) less than 40 ml/min
5. Previous clinical diagnosis of osteomalacia
6. Taking vitamin D preparations
7. Unable to give written informed consent
8. Unable to swallow tablets orally
9. Atrial fibrilation (to provide a more homogeneous aetiology)

Date of first enrolment
28/01/2008

Date of final enrolment
31/08/2008

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Medicine & Therapeutics
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Sponsor information

Organisation
University of Dundee (UK)

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Sponsor type
University/education

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
Chest Heart and Stroke Scotland (UK)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan
The protocol is available from the authors on request but is not available online. 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
Contact for data sharing: Dr Catrina Forde (c.forde@dundee.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2012		Yes	No
Basic results		21/02/2018	26/02/2018	No	No