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Vitamin D therapy to reduce cardiovascular risk in type two diabetes - the next steps

Submission date	Recruitment status	[X] Prospectively registered
11/07/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/02/2018	Nutritional, Metabolic, Endocrine	

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 people with type 2 diabetes. It is not clear what the best dose of vitamin D to use is, or how long the effect of a single large dose lasts for.
The aim of the study is therefore to compare the effect of two different doses of vitamin D with placebo (dummy) and measure whether an effect on blood vessel health and blood pressure can be seen at 8 and 16 weeks after the dose.
Who can participate?
Adults aged 18 years and older with type 2 diabetes

What does the study involve?
The study lasts for 16 weeks. At the start, participants are randomly allocated to one of three groups. They receive two teaspoons of oil, which will contain either 100,000 units vitamin D3, 200,000 units vitamin D3, or a matching placebo (dummy).
Participants are assessed at the start, and 8 weeks and 16 weeks. Each visit lasts 1.5 hours.
At each visit, participants receive some or all of the following depending on which visit it is:
-Blood pressure measurement
-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 the participant is given 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 lowered.
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?
October 2006 to January 2010
Who is funding the study?
Diabetes UK (UK)

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

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2007-003767-51

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2006DM18

Study information

Scientific Title
The effect of different doses of vitamin D(3) on markers of vascular health in patients with type 2 diabetes: a randomised controlled trial

Study objectives
To compare the effect of two different doses of vitamin D3 on vascular function in patients with type two diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Local Research Ethics Committee,10/09/2007, ref: 07/S1401/101

Study design
Double blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Type two diabetes mellitus

Interventions
Single dose of placebo, 100,000 units or 200,000 units of vitamin D3. Each patient will be followed-up for 16 weeks.

Intervention Type
Supplement

Phase
Not Specified

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

Primary outcome measure
Change in endothelial function measured using flow-mediated dilation of the brachial artery (added 26/02/2018: at baseline, 8 and 16 weeks after vitamin D3 treatment).

Secondary outcome measures
Current secondary outcomes (as of 26/02/2018):
All measures are recorded at baseline, 8 and 16 weeks after vitamin D3 treatment.

1. Office blood pressure is measured using an oscillometric system
2. Brain Natriuretic Peptide is measured from a blood sample
3. Insulin sensitivity measured using Homeostasis Model Assessment (HOMA)
4. Parathyroid Hormone (PTH) is measured from a blood sample
5. Vitamin D levels are measured using the 25 hydroxy vitamin D test
6. Calcium levels are measured from a blood sample

Previous secondary outcomes:
Change in:
1. Office and 24-hour Blood Pressure (BP)
2. Brain Natriuretic Peptide (BNP)
3. Heart rate variability
4. Insulin sensitivity (Homeostasis Model Assessment [HOMA])
5. Angiotensin II, renin, aldosterone
6. Parathyroid Hormone (PTH) and 25 hydroxy vitamin D levels

Overall study start date
01/10/2006

Completion date
31/01/2010

Eligibility

Key inclusion criteria
Diagnosis of type two diabetes mellitus.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Taking vitamin D supplements
2. Serum 25 hydroxy vitamin D level of greater than 100 nmol/L
3. Serum creatinine greater than 200 umol/l
4. Liver function tests greater than three times the upper limit of normal
5. Hyper- or hypo-calcaemia (corrected calcium greater than 2.55 or less than 2.15 mmol/l, respectively)
6. Metastatic malignancy
7. Inability to give informed consent

Date of first enrolment

05/06/2008

Date of final enrolment
23/10/2009

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Section of Ageing and Health
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

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
Diabetes UK (UK) (grant ref: BDA: RD06/0003429)

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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	01/10/2010		Yes	No
Basic results		21/02/2018	26/02/2018	No	No