ISRCTN86515510 https://doi.org/10.1186/ISRCTN86515510

Vitamin D supplementation in people at risk of type 2 diabetes

Submission date	Recruitment status	[X] Prospectively registered
23/10/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/11/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/10/2018	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.mrc-epid.cam.ac.uk/Research/Studies/VitaminD/index.html

Contact information

Type(s)
Scientific

Contact name
Prof Graham Hitman

Contact details
Professor of Molecular Medicine & Diabetes
Deputy Director (Research), Centre for Diabetes
Blizard Institute of Cell and Molecular Science
Barts and The London School of Medicine and Dentistry
7th Floor, John Harrison House, Whitechapel
London
United Kingdom
E1 1BB

Additional identifiers

EudraCT/CTIS number
2009-011264-11

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EudraCT 2009-011264-11

Study information

Scientific Title
A randomised double blind placebo controlled phase II multicentre study to investigate the effects of vitamin D2 or D3 supplementation on metabolic parameters in people at risk of type 2 diabetes

Study objectives
Current study hypothesis as of 13/02/2013:
To conduct a four-month randomised controlled trial of vitamin D supplementation in people at risk of diabetes to determine whether:
1. Oral vitamin D supplementation (either vitamin D2 or vitamin D3) can lead to an improvement in glycaemia and related metabolic abnormalities in people at a high risk of developing diabetes and subsequent cardiovascular disease (CVD) compared to the placebo group
2. The feasibility and acceptability of vitamin D supplementation to inform the design of a future randomised controlled trial (RCT) with diabetes and/or cardiovascular endpoints
3. To do an exploratory analysis on the efficacy vitamin D2 as opposed to vitamin D3

Previous study hypothesis until 13/02/2013:
To conduct a four-month pilot randomised controlled trial of vitamin D supplementation in people at risk of diabetes to determine whether:
1. Oral vitamin D supplementation (either vitamin D2 or vitamin D3) can lead to an improvement in glycaemia and related metabolic abnormalities in people at a high risk of developing diabetes and subsequent cardiovascular disease (CVD) compared to the placebo group
2. The feasibility and acceptability of vitamin D supplementation to inform the design of a future randomised controlled trial (RCT) with diabetes and/or cardiovascular endpoints
3. To do an exploratory analysis on the efficacy vitamin D2 as opposed to vitamin D3

Ethics approval required
Old ethics approval format

Ethics approval(s)
Charing Cross Research Ethics Committee ethics approval pending as of 02/11/2009; date of ethics hearing scheduled for 16/11/2009

Study design
Randomised double-blind placebo-controlled multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Type 2 diabetes mellitus

Interventions
Administration of vitamin D2 or D3. Three intervention groups:
1. Cholecalciferol: 100,000 IU once a month for 4 months
2. Ergocalciferol: 100,000 IU once a month for 4 months
3. Placebo (migyol oil): 5 ml once a month for 4 months

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin D2 or D3

Primary outcome measure
Glycaemia as assessed by HbA1c at last visit (4 months)

Secondary outcome measures
Measured at last visit (4 months):
1. Safety of oral vitamin D without a pre-assessment of vitamin D status
2. Feasibility and acceptability of the intervention
3.Quality of life and health economics (8-item short form health survey [SF8] and Euroqol instrument [EQ-5D]) and total body pain (Brief Pain Inventory [BPI])
4. The proportion of participants with a serum 25(OH)D greater than 75 nmol/L
5. Serum 25(OH)D concentrations of 75 - 150 nmol/l measured by an LC-MS/MS (liquid chromatography-tandem mass spectrometry) assay
6. CVD risk score as assessed by UK Prospective Diabetes Study (UKPDS) risk engine
7. Fructosamine
8. Hs-CRP (high sensitivity c-reactive protein)
9. Systolic blood pressure and diastolic blood pressure
10. Random cholesterol, high density lipoprotein (HDL)-cholesterol, ApoA1 and ApoB
11. Waist circumference and body mass index (BMI)
12. Parathyroid hormone (PTH)
13. Urinary Ca:Cr (calcium:creatinine) ratio
14. Arterial stiffness assessed by pulse wave velocity (PWV) (East London participants only)
15. An exploratory analysis on the efficacy vitamin D2 as opposed to vitamin D3

Overall study start date
05/01/2010

Completion date
04/01/2013

Eligibility

Key inclusion criteria
1. Number of participants: 342 (divided between Cambridge and East London)
2. Age 30 - 75 years, either sex
3. All ethnic groups
4. People at risk of developing type two diabetes (T2D) as defined by:
4.1. The Cambridge Risk Score (CRS). The CRS cut-offs would be 0.236 for the Black/Caribbean population, 0.127 for South Asians and 0.199 for Caucasians. For other groups the cut-off for Caucasians will be used; or
4.2. Impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) defined by current World Health Organization (WHO) criteria, where this information is available in medical records, or in the records of studies in which participants have consented to being re-approached to consider participating in future studies; or
4.3. Non-diabetic hyperglycaemia as defined by HbA1c between 5.5% to 6.49%, where this information is available in medical records, or in the records of studies in which participants have consented to being re-approached to consider participating in future studies.
5. Can provide informed consent for participation in the trial

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
342

Key exclusion criteria
1. Known T2D or use of oral hypoglycaemic agents (GP records, participant history)
2. Random blood glucose during initial screening greater than 11 mmol/l (screening)
3. Known intolerance to vitamin D2 or D3 (GP records, participant history)
4. Currently taking vitamin D supplements (GP records, participant history)
5. Prior history of hypercalcaemia (serum calcium greater than 2.65 mmol/l) (GP records, participant history) or point of care ionised calcium greater than 1.3 mmol/l (screening)
6. Stage 4 or worse chronic kidney disease (estimated glomerular filtration rate [eGFR] less than 30 ml/min) (GP records, participant history)
7. History of significant liver disease (aspartate aminotransferase [AST] greater than 3 x upper limit of normal [ULN] or serum bilirubin greater than 2.5 x ULN) (GP records, participant history)
8. Past or current history of renal stones (GP records, participant history)
9. Known hyperparathyroidism (GP records, participant history)
10. Known active sarcoidosis, tuberculosis or malignancy (GP records, participant history)
11. Taking cardiac glycosides, thiazide diuretics or corticosteroids in the past one month (GP records, participant history)

12. Documented anaemia of less than 11 g% or known haemoglobinopathy such as sickle cell anaemia and beta or alpha thalassemia (GP records, participant history)
13. Planned travel out of the London area or Cambridge (depending of site of recruitment) within 8 weeks of enrolment such that it will disrupt monitoring of the participant (participant history)
14. Breast feeding, pregnancy or planning a pregnancy (participant history)

Date of first enrolment
05/01/2010

Date of final enrolment
04/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts and The London School of Medicine and Dentistry
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Queen Mary University of London/Barts and The London NHS Trust (UK)

Sponsor details
Joint R&D office
Queen Mary's Innovation Centre
Lower Ground Floor
5 Walden Street
London
England
United Kingdom
E1 2AT

Sponsor type
Hospital/treatment centre

Website

http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
NHS Tower Hamlets and MRC Epidemiology Centre (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/10/2013		Yes	No
Results article	results	01/04/2016		Yes	No