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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

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2009-011264-11

Protocol serial number
EudraCT

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

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled multicentre trial

Study type(s)
Prevention

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(s)
Glycaemia as assessed by HbA1c at last visit (4 months)

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Barts and The London School of Medicine and Dentistry
London
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Sponsor information

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

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

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

Results and Publications

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?
Results article	results	01/04/2016		Yes	No
Protocol article	protocol	23/10/2013		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes