ISRCTN18522562 https://doi.org/10.1186/ISRCTN18522562

Can vitamin D replacement reduce insulin resistance in South Asians with vitamin D deficiency?

Submission date
20/10/2011

Recruitment status
Stopped

Registration date
20/10/2011

Overall study status
Stopped

Last Edited
23/04/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims?
Vitamin D is involved with body defences and may protect us from developing Type 2 diabetes. If people are low on blood levels of Vitamin D, they are more likely to develop Type 2 Diabetes in the future. Compared with their white European counterparts, Leicester South Asians have less than half the circulating Vitamin D and are twice as likely to develop diabetes. Can giving Vitamin D prevent or reduce risk of developing diabetes? We aim to test whether replacing Vitamin D reduces risk of developing diabetes in 100 south Asians. We will measure a marker of insulin action (HOMA-IR) before and after giving Vitamin D therapy. Changes in this marker indicate either higher or lower risk of diabetes.

Who can participate?
We can invite you to come to screening if you are:
South Asian man or woman (originating from India, Pakistan, Bangladesh or Sri Lanka)
Aged 25-75 years
Not taking Vitamin D/ Calcium medicines for 1 month
Able to commit to a six month study

What does the study involve?
We will check your blood Vitamin D level and a marker of insulin action (HOMA-IR). If your Vitamin D level is low and you are at risk of diabetes we can recruit you into the study. We will run some safety checks first. If selected for the study, you will be randomly allocated to one of two groups: the first receives higher dose Vitamin D and the second receives lower dose Vitamin D in a 6 month study. Whichever group you are allocated, you will receive some Vitamin D therapy (that is known to be safe and approved for research studies) to improve your low Vitamin D level.Taking the Vitamin D therapy involves drinking some liquid drops (maximum 10ml two tea spoons) once every six weeks and taking a Vitamin D tablet everyday for 6 months. The liquid drops will contain either a higher dose Vitamin D or a placebo (dummy) depending on the group you are allocated to. The daily Vitamin D tablet will be the same for all participants. During the study we will ask to see you to check your Vitamin D level.

What are the possible benefits and risks of participating?
The benefits from entering this study include finding out your Vitamin D level and whether you are at risk of diabetes. If you are found eligible for the study then you will have a full diabetes test and some education about reducing the risk of diabetes. You will also receive Vitamin D therapy which is aimed at trying to improve your vitamin D level. You also have the opportunity to participate in research that may one day help the South Asian community. The risks of entering this study include discomfort during blood tests (pain, bleeding and swelling). We do not expect the Vitamin D levels in your body to become too high and cause problems, but we will perform checks to reduce the chances of this happening. Side effects of any Vitamin D tablet include feeling thirsty, passing more water than normal, abdominal or bone pain.

Where is the study run from?
The study will be run from University Hospitals of Leicester (both Leicester General Hospital and Leicester Royal Infirmary). We may to see you at either of these sites.

When is study starting and how long is it expected to run for?
The study will last six months and run any time between 2012 and 2013.

Who is funding the study?
The study is funded in part by the Novo Nordisk Research Foundation.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2010-024213-31

IRAS number

ClinicalTrials.gov number
NCT01385345

Secondary identifying numbers
10624

Study information

Scientific Title
Can vitamin D replacement reduce insulin resistance in South Asians with vitamin D deficiency? A randomised controlled trial.

Acronym
VITALITY

Study objectives
This study will test the hypothesis that 6 months of periodic high dose Vitamin D3 replacement (200,000 and 100,000 units cholecalciferol, oral liquid drops at 6 to 8 week intervals) followed in-between by daily 1000 units, decreases insulin resistance by HOMA2-IR = 0.36, in comparison to control, standard dose Vitamin D3 1000IU/ day (45) for 6 months, in South Asians with both Vitamin D deficiency (defined as 25 Hydroxy vitamin D < 25nmol/l) and insulin resistance (defined as HOMA1 -IR= 1.93).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire and Rutland Research Ethics Committee, 07/03/2011 ref: 11 /HO406/6

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Diabetes Research Network: obesity, prevention/screening, pre diabetes in ethnic minorities

Interventions
We will run a 6 month randomised control trial of Vitamin D3 replacement:
Intervention arm:
Within each period of 6 to 8 weeks we now wish to give a higher dose on day 1 followed by a maintenance daily dose for the remainder of the period.

1. Month 0: 200,000 units stat day 1 followed by 1,000 units/ day for rest of period
2. Month 1.5 six weeks later: 100,000 units stat day 1 followed by 1,000 units/ day for rest of period
3. Month 3 six weeks later: same as (b)
4. Month 5 two months later (V6): same as (2)
5. Month 6 study exit and finish

Control arm:
1,000 units a day for six months then study exit and finish

Intervention Type
Supplement

Primary outcome measure
This study will test the hypothesis that 6 months of periodic high dose Vitamin D3 replacement (200,000 and 100,000 units cholecalciferol, oral liquid drops at 6 to 8 week intervals) followed in-between by daily 1000 units, decreases insulin resistance by HOMA2-IR ≥ 0.36, in comparison to control, standard dose Vitamin D3 1000IU/ day for 6 months, in south Asians with both Vitamin D deficiency (defined as 25 Hydroxy vitamin D < 25nmol/l) and insulin resistance (defined as HOMA1 -IR≥ 1.93).

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2012

Completion date
31/10/2013

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. 25 - 75 year old South Asian (Bangladeshi, Indian or Pakistani), men or women
2. A low vitamin D level (defined by a specific marker, 25(OH)VitD <25 nmol/L)
3. Insulin resistance, defined as HOMA1IR = 1.93

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100; Description: South Asians with HOMA-IR>1.93

Key exclusion criteria
1. Those who have been told by a doctor they have diabetes (Type 1 or 2).
2. Those who developed new diabetes detected on the Screening Visit fasting glucose test (such participants will be offered a confirmatory test to determine if they have diabetes with an oral glucose tolerance test) or the oral glucose tolerance test at baseline Visit. Any individual with new diabetes will have follow up arranged with a doctor. If the confirmatory test does not show new diabetes, the participant will is elegible to reenter the study.
3. HbA1c > 6.9% which is suggestive of diabetes.
4. Preexisting calcium and/or Vitamin D tablets (D2 ergocalciferol or D3 cholecalciferol) / therapy (e.g. intramuscular injections, oral liquid preparations) or previous adverse reaction to Vitamin D (D2 or D3). Any individual who has previously been on these therapy must have been off Vitamin D/ Calcuim for at least six months.
5. Pregnancy or breast feeding females, or actively trying/ intending to become pregnant during the planned six month trial.
6. A history of known or newly detected hypercalcaemia or hypocalcaemia, hyperparathyroidism (that induce high
calcium levels), kidney stones or other kidney problems/ low kidney function (eGFR<60) or known history of liver problems/ disorders
7. A history of known bone diseases (including osteoporosis, osteomalacia) or muscle diseases/ myopathies
8. Any participant discovered to have new kidney/ liver/ bone or other health problems discovered during Screening or baseline visit. Such individuals will have approprioate follow up organsied. A raised PTH will be considered in the clinical context of ALP and Vitamin D level (i.e. may be excluded)
9. Terminal illness, malignancy or physical inability to give consent (not language barriers)
10. Taking medications which may interfere with Vitamin D metabolism (phenytoin, carbamazepine, primidone and barbituates) or potentially leading to other problems (bendroflumethiazide, digoxin)
11. Participants unable to commit time for the entire six month study (e.g. holiday abroad, work commitments)
12. Actively taking part in another interventional study (e.g. medication, lifestyle RCTs); observational and cross-sectional studies are still permitted

Date of first enrolment
01/01/2012

Date of final enrolment
31/10/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Leicester Diabetes Centre (Broadleaf)
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University of Leicester

Sponsor details
University Road
Leicester
England
United Kingdom
LE1 7RH

Sponsor type
University/education

Website
http://www2.le.ac.uk/

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Research organisation

Funder Name
Novo Nordisk UK Research Foundation (UK)

Alternative Name(s)
The Novo Nordisk UK Research Foundation, ovo Nordisk Research Foundation UK, NNUKRF

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
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?
Basic results				No	No
Thesis results				No	No