

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

<b>Submission date</b> 20/10/2011	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/10/2011	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/04/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 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?

Dr Samiul Mostafa (clinical research fellow in Diabetes Medicine and Specialist Registrar, SpR)  
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## Contact information

### Type(s)

Scientific

### Contact name

Prof Melanie Davies

### Contact details

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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  $\text{HOMA2-IR} \geq 0.36$ , 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  $\text{HOMA1-IR} \geq 1.93$ ).

## **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,  $25(\text{OH})\text{VitD} < 25 \text{ nmol/L}$ )
3. Insulin resistance, defined as  $\text{HOMA1IR} = 1.93$

## **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 be eligible 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/ Calcium 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 appropriate follow up organised. 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?
<a href="#">Basic results</a>				No	No
<a href="#">Thesis results</a>				No	No