

# A comparison of the absorption of Vitamin D with and without pollen

<b>Submission date</b> 02/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/12/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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 deficiency has become a great problem because of lack of sunlight exposure and the relative scarcity of vitamin D in the diet. This study aims to determine whether encapsulation of vitamin D within spores could increase its absorption in the blood in normal healthy volunteers.

### Who can participate?

Six normal healthy volunteers who are not taking any medications or over the counter supplements will be recruited.

### What does the study involve?

The participants will be randomly allocated either to vitamin D with spore encapsulation or vitamin D without spore encapsulation. Participants will come to the centre twice to test each of the vitamin D preparations and each time we will ask you to attend without having had anything to eat or drink, other than water, from the previous night. We will place a plastic tube (cannula) in your arm to allow blood to be taken without the need for multiple needles to be used. A sample of blood will be taken, after which you will take the first vitamin D supplement.

Blood samples will be taken fasting (time 0), then at 15, 30, 45, 60, 120, 180 and 240 minutes after taking the supplement. Participants will be then given a washout period before being asked to take the other supplement and blood sampling will be repeated as described above. The blood samples that will be taken will be labelled with a simple number so that they cannot be traced back to you. All samples will be sent for vitamin D analysis at the laboratories at Hull Royal Infirmary. Any additional samples will be destroyed after the vitamin D levels have been measured.

We will take your height, weight and blood pressure as part of the study.

### What are the possible benefits and risks of participating?

For most people needle punctures for blood draws do not cause any serious problems. Some people feel faint, and there may be some pain and bruising (or, very rarely, infection) where the needle goes in. Both pollen and vitamin D supplements are freely available on the market and shouldn't cause any allergic reactions. Please let us know if you have had any problems in the past. All staff in the Clinical Trial Units are qualified to deal with adverse events and there will be

a doctor present in the event of something going wrong. You may withdraw from participation in the project at any time and without any disadvantage to yourself of any kind.

Where is the study run from?

Clinical Trials Unit, HONEI project, University of Hull.

When is study starting and how long is it expected to run for?

The study began in May 2012 and is expected to run for 2 months.

Who is funding the study?

Diabetes Endowment Fund, University of Hull.

Who is the main contact?

Dr T Sathyapalan

thozhukat.sathyapalan@hyms.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Thozhukat Sathyapalan

### Contact details

Michael White Diabetes Centre

Hull Royal Infirmary

220 - 236 Anlaby Road

Hull

United Kingdom

HU3 2RW

## Additional identifiers

### Protocol serial number

Version 1. 01/07/2011

## Study information

### Scientific Title

A comparison of the absorption of ergocalciferol with and without pollen: a randomised controlled trial

### Study objectives

Encapsulating vitamin D with exine microcapsules enhance its bioavailability in the blood in normal healthy volunteers

### Ethics approval required

Old ethics approval format

**Ethics approval(s)**

Hull York Medical School, University of Hull Ethics Committee, 12 October 2011

**Study design**

Double blind randomised cross over study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Vitamin D absorption in healthy volunteers

**Interventions**

Participants are randomised to either vitamin D with spore encapsulation or vitamin D without spore encapsulation.

The vitamin D supplement will be taken on an empty stomach after participants have fasted for 10 hours. Blood samples will be taken fasting (time 0), then at 15, 30, 45, 60, 120, 180 and 240 minutes after taking the supplement.

Participants will be then given a 1 month washout period before being asked to take the other supplement and blood sampling was repeated as described above.

**Intervention Type**

Supplement

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Vitamin D

**Primary outcome(s)**

Area under the curve for 25-hydroxy (25OH) vitamin D levels at (time 0), then at 15, 30, 45, 60, 120, 180 and 240 minutes after taking the supplement.

**Key secondary outcome(s)**

1. Adjusted Calcium
2. Parathyroid hormone

At (time 0), then at 15, 30, 45, 60, 120, 180 and 240 minutes after taking the supplement.

**Completion date**

30/07/2012

**Eligibility**

**Key inclusion criteria**

1. Male or Female subjects between the age of 35-65
2. No concomitant medication or vitamin supplements
3. No concomitant disease processes
4. Body Mass Index 21- 29kg/m<sup>2</sup>
5. Systolic blood pressure ≤140 mm Hg and diastolic pressure ≤85 mm Hg

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Concomitant medication or disease processes
2. Body Mass Index <21 and > 29kg/m<sup>2</sup>
3. Systolic blood pressure >140 mm Hg and or a diastolic pressure >85 mm Hg
4. Subjects taking vitamin D supplements
5. Subjects not willing or able to fast until 12 noon (a total of 14 hours)
6. Subjects taking any food supplements including pollen

**Date of first enrolment**

01/05/2012

**Date of final enrolment**

30/07/2012

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Michael White Diabetes Centre**

Hull

United Kingdom

HU3 2RW

**Sponsor information**

**Organisation**

University of Hull (UK)

**ROR**

<https://ror.org/04nkhwh30>

**Funder(s)****Funder type**

University/education

**Funder Name**

University of Hull (UK) - Diabetes Endowment Fund

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration