

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

Submission date 02/07/2012	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 16/07/2012	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 06/12/2019	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data
		☐ 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

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Contact information

Type(s)

Scientific

Contact name

Dr Thozhukat Sathyapalan

Contact details

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Hull Royal Infirmary

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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

Primary study design

Interventional

Study design

Double blind randomised cross over study

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/m²
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/m²
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