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

Submission date
02/07/2012

Recruitment status
No longer recruiting

Registration date
16/07/2012

Overall study status
Completed

Last Edited
06/12/2019

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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 shouldnt 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
Michael White Diabetes Centre
Hull Royal Infirmary
220 - 236 Anlaby Road
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United Kingdom
HU3 2RW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
1. Adjusted Calcium
2. Parathyroid hormone

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

Overall study start date
01/05/2012

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

Age group
Adult

Sex
Both

Target number of participants
6

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
England

United Kingdom

Study participating centre
Michael White Diabetes Centre
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
University of Hull (UK)

Sponsor details
c/o Mr Jonathan Cant
Research and Contracts Manager
Research Funding Office
The Enterprise Centre
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England
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HU6 7RX

Sponsor type
University/education

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
University/education

Funder Name
University of Hull (UK) - Diabetes Endowment Fund

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