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Comparison of the bioavailability of vitamin D2 and D3

Submission date	Recruitment status	[_] Prospectively registered
24/05/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/08/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/09/2015	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Vitamin D is essential for good health, because it helps our bodies to absorb calcium from the diet. There is a lot of evidence that having enough vitamin D can help prevent against many diseases, such as heart disease, bone diseases and cancer. Although vitamins generally come from the diet, in the case of vitamin D, the majority of people actually get most of it from sunlight. When the sun shines on our skin, a reaction in the body is triggered, producing a form of vitamin D called cholecalciferol (also called vitamin D3). Another important form of vitamin D is ergocalciferol (also called vitamin D2), which is produced in plants. Studies have shown that in the winter months, many people in the UK suffer from a lack of vitamin D (vitamin D deficiency) because of the lack of sun exposure. It can be hard to take in vitamin D in the diet, as it is not naturally present in many foods. A possible solution is to fortify food or drink with vitamin D2 or D3. The aim of this study is to find out whether the concentrations of vitamin D in the blood can be maintained by regularly consuming D2 or D3, and if one is better than the other.

Who can participate?

Healthy adults among the staff and students of King’s College London (UK).

What does the study involve?

Participants are randomly allocated into one of five groups. Participants in the first group receive sachets to make hot malted milk drinks (Horlicks) which does not have any extra ingredients (placebo). Participants in the other four groups are also given sachets to make malted milk drinks, but theirs contain additional vitamin D (5ug or 10ug of either D2 or D3). Participants in all groups are asked to drink one sachet every day for four weeks. Blood samples are taken from all participants, twice at the start of the study and then weekly over the four weeks to measure the concentration of vitamin D in the blood.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

Metabolic Research Unit, King's College London (UK)

When is the study starting and how long is it expected to run for?
February 2011 to April 2011

Who is funding the study?
GlaxoSmithKline (UK)

Who is the main contact?
Professor Tom Sanders
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
RHS00976

Study information

Scientific Title
Comparison of the bioavailability of vitamin D2 and vitamin D3 in healthy volunteers when consumed at different levels in a malt drink

Study objectives
This study will investigate whether the seasonal fall in serum serum 25-hydroxyvitamin D concentrations [25(OH)D] that occurs in the winter months can be prevented by the regular consumption of ergocalciferol or cholecalciferol in a fortified drink.
Vitamin D is a determinant of calcium homeostasis and therefore changes in calcium and parathyroid hormone concentrations were also investigated.

Ethics approval required
Old ethics approval format

Ethics approval(s)

South East London REC1 February 2011, ref: 10/H0804/91

Primary study design
Interventional

Study design
Parallel randomized placebo controlled double blind design

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Vitamin D supplementation

Interventions
1. Participants were randomly allocated to placebo or one of 4 experimental treatments of vitamin D:
1.1. 5ug cholecalciferol or
1.2. 5ug ergocalciferol or
1.3. 10ug cholecalciferol or
1.4. 10ug ergocalciferol
2. The vitamin D or placebo was administered as a malted milk drink and consumed once a day for 28 days

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cholecalciferol, ergocalciferol

Primary outcome(s)
Change in serum 25(OH)D concentrations

Key secondary outcome(s)
Change in calcium and parathyroid hormone concentrations

Completion date
13/04/2011

Eligibility

Key inclusion criteria
1. Healthy males or females
2. Ages of 18 - 65 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Seated blood pressure >160/105 mm Hg
2. Body Mass Index <18.5 and >35 kg/m2
3. Taking vitamin and mineral supplements (including cod-liver oil), or prescription calcium /vitamin D
4. Recent exposure to high UVB light (since 1 December 2010)
5. Intolerance to study product (lactose, milk protein)
6. Chronic renal, liver or inflammatory bowel disease
7. Diabetes
8. Unwilling to follow the protocol and/or give informed consent
9. Unwilling to restrict consumption of oily fish to no more than 2 portions of oily fish per week

Date of first enrolment
22/02/2011

Date of final enrolment
13/04/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
London
United Kingdom
SE1 9NH

Sponsor information

Organisation
GlaxoSmithKline (UK)

ROR
https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (ref: RHS00976)

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2012		Yes	No
HRA research summary			28/06/2023	No	No