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DRISK Study

Submission date	Recruitment status	[ ] Prospectively registered
29/08/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/09/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/08/2020	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Low vitamin D levels in the blood have been shown to be associated with an increased risk of cardiovascular disease (CVD). The aim of this trial is to investigate if vitamin D2 supplements in a malted milk drink compared to placebo (malted milk drink with no vitamin D added) is associated with a change in factors that are associated with the risk of CVD.

Who can participate?
Healthy men and healthy post-menopausal women aged 50-70 years.

What does the study involve?
Participants will be randomly allocated to a placebo or to vitamin D2 provided as a malted milk drink for 3 months.

What are the possible benefits and risks of participating?
Participants screened for heart disease and diabetes risk factors. There are no expected side effects of the treatment.

Where is the study run from?
Metabolic Unit at Kings College Hospital and the Clinical Research Facility at St Thomas Hospital.

When is the study starting and how long is it expected to run for?
The study will have two stages; one will run from January - May 2012 and the second from January -May 2013.

Who is funding the study?
GlaxoSmithKline (GSK) Consumer Healthcare

Who is the main contact?
Prof Thomas Sanders
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Contact information

Type(s)

Scientific

Contact name
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Additional identifiers

Protocol serial number
RH01372

Study information

Scientific Title
The effect of low dose vitamin D2, provided in a fortified malted milk drink, on cardiovascular RISK

Acronym
DRISK

Study objectives
1. Endothelial function will be improved with vitamin D provided in a malted milk drink
2. Vitamin D will improve cardiovascular risk profile

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Research Ethics Committee London - Westminster, 06/12/2011, ref: 11/LO/1626

Study design
Randomised placebo controlled parallel double blind study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Cardiovascular disease risk

Interventions

Current interventions as of 18/02/2013:
At baseline subjects will be given sachets of a malted milk drink containing 24mcg vitamin D2, or placebo (malted milk drink without vitamin D added). They will be asked to consume 3 sachets a week for 3 months, to provide an intake equivalent to 10 mcg a day in the treatment group.

18/02/2013: Please note that this change was a correction due to an error in the original application. The intervention was 3 sachets a week for 3 months since the trial started in January 2012.

Previous interventions until 18/02/2013:
At baseline subjects will be given sachets of a malted milk drink containing 24mcg vitamin D2, or placebo (malted milk drink without vitamin D added). They will be asked to consume 3 sachets a day for 3 months, to provide an intake equivalent to 10 mcg a day in the treatment group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Endothelial function as measured by flow mediated dilatation (FMD).

Key secondary outcome(s))
1. Cardiovascular risk profile (arterial stiffness measured by Pulse Wave Velocity (PWV) using a cuff on the upper arm and thigh, and Doppler probe on the neck, ambulatory blood pressure as measured by ambulatory blood pressure monitoring (ABP), fasting lipid profile, C - reactive protein as an indicator of low grade inflammation, MMP-9 and fibrinogen).
2. Markers of compliance Ca2+ , PTH, 25(OH)D2 and 25(OH)D3 concentrations and BMI.
3. We will use the Homeostasis Model Assessment (HOMA) to estimate beta cell function and insulin sensitivity based on measurements of c-peptide and fasting glucose.
4. As it has been suggested that vitamin D supplementation suppresses renin secretion, we shall measure plasma renin concentrations.
5. We will also measure cognitive function using a series of computerised questions.

Completion date
30/04/2013

Eligibility

Key inclusion criteria
Participants will be healthy men or post-menopausal women aged between 50 and 70 years.
A fasting blood sample will be collected to determine normal liver function, blood glucose and haematology.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
41

Key exclusion criteria
1. A reported history of angina pectoris, myocardial infarction, stroke, peripheral vascular disease, arterial fibrillation, congenital heart defects or congenital heart disease (this will be assessed using the telephone questionnaire and confirmed with the lifestyle questionnaire completed at screening)
2. An overall risk of cardiovascular disease over the next ten years of >20% assessed according to QRISK2 (www.qrisk.org)
2.Ambulatory blood pressure >150/95 mm Hg (assessed by ambulatory blood pressure monitoring)
3. Current use of medication for lowering blood cholesterol (statins) or blood pressure
4. Type 1 or Type 2 diabetes mellitus (fasting blood glucose > 7.0 mmol/L)
5. Chronic renal, liver or inflammatory bowel disease
6. Current cigarette smoker
7. Underweight or morbidly obese (Body Mass Index <18.5 and >35 kg/m2)
8. Prolonged exposure to high UV-b light since Nov 2011
9. Going to a lower latitude country, or using a tanning sunbed during the study period
10. Intolerance to study product (lactose, milk protein)
11. Taking vitamin and mineral supplements (including cod-liver oil), or prescription calcium /vitamin D
12. Unwilling to restrict consumption of oily fish to no more than 2 portions per week
13. Consuming soya milk
14. Unwilling to follow the protocol and/or give informed consent

Date of first enrolment
03/01/2012

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

King's College London
London
United Kingdom
SE1 8WA

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Biotechnology and Biological Sciences Research Council [BBSRC] (UK)

Funder Name
GlaxoSmithKline CASE Studentship ref: RH01372 (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration