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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
Prof Thomas Sanders

### Contact details
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## Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design

Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Prevention

## 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
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 measure
Endothelial function as measured by flow mediated dilatation (FMD).

## Secondary outcome measures
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  $Ca^{2+}$ , 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.

### Overall study start date
03/01/2012

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
40

### 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**
England

United Kingdom

**Study participating centre**
**King's College London**
London
United Kingdom
SE1 8WA

# Sponsor information

**Organisation**
King's College London (UK)

**Sponsor details**
Franklin-Wilkins Building
Stamford Street
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England
United Kingdom
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**Sponsor type**
University/education

**Website**
http://www.kcl.ac.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

**Publication and dissemination plan**
Not provided at time of registration

2014 results published in thesis [https://kclpure.kcl.ac.uk/portal/files/61288715/2014_Fry_Catherine_1055698_ethesis.pdf]

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration