# Effects of increased egg consumption as part of a weight-reducing diet on blood cholesterol and related biomarkers of coronary heart disease risk

| Submission date                     | Recruitment status  No longer recruiting             | <ul><li>Prospectively registered</li></ul> |  |  |
|-------------------------------------|--|--|--|--|
| 22/09/2005                          |  | ☐ Protocol                                 |  |  |
| <b>Registration date</b> 05/10/2005 | Overall study status Completed                       | Statistical analysis plan                  |  |  |
|                                     |  | [X] Results                                |  |  |
| <b>Last Edited</b> 13/10/2009       | Condition category Nutritional, Metabolic, Endocrine | [] Individual participant data             |  |  |

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Bruce Griffin

#### Contact details

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# Additional identifiers

Protocol serial number

N/A

# Study information

#### Scientific Title

#### Study objectives

- 1. Consumption of 2 eggs per day for 12 weeks will produce no significant effect on plasma cholesterol and other related biomarkers of CHD risk when accompanied by weight-loss induced by an energy-restricted diet
- 2. That egg consumption will promote greater weight-loss with an energy-restricted diet than an energy-restricted diet alone

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics committee (ref: EC/2004/109/SBMS)

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Overweight

#### **Interventions**

Test group: 2 small eggs/day + energy-restricted diet (~500 Kcal/day following British Heart Foundation [BHF] quidelines).

Control group: energy-restricted diet alone.

12 week intervention.

#### Intervention Type

Drug

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

Eggs

#### Primary outcome(s)

- 1. Total plasma cholesterol
- 2. Low-density lipoprotein (LDL) cholesterol
- 3. Body weight

#### Key secondary outcome(s))

Plasma cholesterol precursors (mevalonate and lathosterol) and plant sterols (beta-sitosterol and campesterol) as markers of cholesterol synthesis and absorption respectively

#### Completion date

01/04/2006

# Eligibility

#### Key inclusion criteria

- 1. Healthy adult male and females aged 18-55 years
- 2. Body Mass Index (BMI) that classifies them as being overweight >25, <40

#### Participant type(s)

**Patient** 

### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

55 years

#### Sex

All

#### Key exclusion criteria

- 1. BMI >40 (morbid obesity)
- 2. Total plasma cholesterol >6.5 mM
- 3. No prescribed medication
- 4. No dietary supplements including 'cholesterol-lowering' foods (e.g. benecol or flora proactive) or existing diets or having lost >3 kg in preceding 2 months

#### Date of first enrolment

01/05/2005

#### Date of final enrolment

01/04/2006

## Locations

#### Countries of recruitment

**United Kingdom** 

England

Study participating centre School of Biomedical & Molecular Sciences Guildford United Kingdom GU2 7XH

# Sponsor information

#### Organisation

British Egg Information Service (UK)

#### **ROR**

https://ror.org/02an8as91

# Funder(s)

## Funder type

Other

#### Funder Name

British Egg Information Service (UK)

#### **Funder Name**

University of Surrey (UK) - Finance Office, RC4022

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

| Output type     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/09/2008   |            | Yes            | No              |