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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
22/09/2005

Recruitment status
No longer recruiting

Registration date
05/10/2005

Overall study status
Completed

Last Edited
13/10/2009

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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] guidelines).
Control group: energy-restricted diet alone.
12 week intervention.

Intervention Type
Drug

Phase
Not Specified

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

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

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

Overall study start date
01/05/2005

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
50

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
England

United Kingdom

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

Sponsor information

Organisation
British Egg Information Service (UK)

Sponsor details
126-128 Cromwell Road
London
United Kingdom
SW7 4ET
+44 (0)20 7370 7411
info@britegg.co.uk

Sponsor type
Other

Website
http://www.britegg.co.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

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

Study outputs

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