

Effect of plant sterol margarines on serum cholesterol in everyday practice

Submission date 19/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/10/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Michael Moore

Contact details
Primary Medical Care
Aldermoor Close
Southampton
United Kingdom
SO16 1ST

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4/3/03

Study information

Scientific Title

An open randomised trial of the effect of plant sterol margarines on serum cholesterol in everyday practice

Acronym

SPREADS

Study objectives

1. To estimate the effect of advice to use a plant sterol margarine in a free living population when compared to a polyunsaturated margarine among those with hypercholesterolaemia.
2. To estimate whether sterols reduce beta-carotene levels and if this can be counteracted by an increase in fruit and vegetable consumption.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. South Wiltshire Ethics Committee, approved in 2002, ref: SA231/2002
2. Southampton City Ethics Committee, approved in 2002, ref: 328/02/w

Study design

Open randomised crossover trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Hypercholesterolaemia in adults

Interventions

Polyunsaturated margarine or sterol enriched margarine taken for 6 weeks with a crossover design (no washout period).

Total duration of interventions and follow-up: 12 weeks

Intervention Type

Supplement

Primary outcome measure

Serum cholesterol and beta-carotene assessed at baseline, 6 and 12 weeks

Secondary outcome measures

High-density lipoprotein (HDL) cholesterol, total cholesterol (TC)/HDL ratio, assessed at baseline, 6 and 12 weeks

Overall study start date

01/09/2003

Completion date

31/03/2007

Eligibility

Key inclusion criteria

Adult (both males and females) over 18 with cholesterol >6 mmol

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

232

Key exclusion criteria

Those considered unsuitable by their GP e.g., cancer, acute or chronic psychotic disorder or dementia

Date of first enrolment

01/09/2003

Date of final enrolment

31/03/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Primary Medical Care
Southampton
United Kingdom
SO16 1ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
University Road
Southampton
England
United Kingdom
so17 1bj

Sponsor type
University/education

Website
<http://www.soton.ac.uk/>

ROR
<https://ror.org/01ryk1543>

Funder(s)

Funder type
University/education

Funder Name
Royal College of General Practitioners (RCGP) - Scientific Foundation Board (UK)

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