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Effect of plant sterol margarines on serum cholesterol in everyday practice

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

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
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
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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