ISRCTN61150880 https://doi.org/10.1186/ISRCTN61150880

Effect of plant sterol margarines on serum cholesterol in everyday practice

Submission date
19/02/2009

Recruitment status
No longer recruiting

Registration date
31/03/2009

Overall study status
Completed

Last Edited
13/10/2017

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Open randomised crossover trial

Study type(s)
Treatment

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

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

Completion date
31/03/2007

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
University of Southampton (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration