

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

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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

Study design

Open randomised crossover trial

Primary study design

Interventional

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