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Effect of milk fortified with plant sterols on the lipid profile of patients with moderate hypercholesterolemia

Submission date	Recruitment status	[ ] Prospectively registered
22/09/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/10/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/10/2010	Nutritional, Metabolic, Endocrine	[ ] 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
AGR 17625

Study information

Scientific Title
Effect of milk fortified with plant sterols on the lipid profile and serum non-cholesterol sterols of patients with moderate hypercholesterolemia: A randomised, crossover feeding study

Study objectives
Plant sterols (PS) are constituents of plants that chemically resemble cholesterol and have cholesterol lowering properties. Traditionally, PS have been incorporated into high-fat foods to facilitate their solubility.

Two hypotheses are tested:
1. Compared to a placebo skimmed milk, the consumption of skimmed milk enriched with PS and skimmed plus vegetable fat milk enriched with PS (both low-fat vehicles) will have a hypocholesterolemic effect similar to that of fatty foods fortified with similar doses of PS
2. Baseline serum levels of PS indicative of high intestinal cholesterol absorption will be associated with an enhanced cholesterol-lowering response to consumption of PS

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of the Hospital Clinic of Barcelona approved on the 16th of December 2003 (ref: CEIC 1801)

Study design
Randomised crossover feeding intervention study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Dyslipidemia / Nutrition

Interventions
All subjects will participate in each of 3 intervention periods lasting 4 weeks each. The sequence of the interventions will be randomised:
1. 500 ml/day of skimmed milk with 2 g PS
2. 500 ml/day of skimmed plus vegetable fat milk with 2 g PS
3. 500 ml/day of placebo skimmed milk
Each intervention period will be preceded by a 4-week run-in period with placebo milk.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

1. Effects on the serum lipid profile
2. Effects on serum non-cholesterol sterol concentrations
2.1. demosterol
2.2. lathosterol
2.3. lanosterol
2.4. campesterol
2.5. sitosterol

Measurements are taken at baseline, after the run-in period, and at the end of the three 4-week diet intervention periods.

Key secondary outcome(s))
Influence of baseline serum non-cholesterol concentrations and their on-treatment changes on the cholesterol-lowering response

Measurements are taken at the same time points than primary outcome measures.

Completion date
31/10/2004

Eligibility

Key inclusion criteria
1. Men and women with moderate hypercholesterolemia
2. Aged between 18 and 75 years
3. Body mass index (BMI) <31 kg/m2
4. Serum total cholesterol between 4.91 and 7.75 mmol/L
5. Low Density Lipoprotein (LDL) cholesterol >3.36 mmol/L
6. Triglycerides <3.39 mmol/L
7. Participants can be under stable lipid-lowering drug treatment (statins or fibrates, statins at doses of no more than simvastatin 40 mg/day or equivalent) or cardiac medication in patients with previous cardiovascular disease
8. Written informed consent. Participants were given a leaflet with explanation of the study, including reasons for masking the contents of the milk product, and information on how to contact investigators if necessary.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Subjects on a weight-losing diet
2. Familial hypercholesterolemia
3. Established type 2 diabetes
4. Lactose intolerance
5. Consumption of products that can influence cholesterol metabolism (other than statins and fibrates), such as
5.1. resins
5.2. ezetimibe
5.3. psyllium products
5.4. fish oil products
5.5. soya lecithin
5.6 phytoestrogens

Date of first enrolment
01/02/2004

Date of final enrolment
31/10/2004

Locations

Countries of recruitment
Spain

Study participating centre
Lipid Clinic
Barcelona
Spain
08036

Sponsor information

Organisation
Unilever R&D (Netherlands)

ROR
https://ror.org/02436cs38

Funder(s)

Funder type
Industry

Funder Name
Unilever R&D Vlaardingen BV (Netherlands)

Funder Name
Spanish Ministry of Science and Innovation (Instituto de Salud Carlos III [CIBER]) (Spain) - Pathophysiology of Obesity and Nutrition (Fisiopatología de la Obesidad y Nutrición [CIBERobn])

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration