

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

Submission date

22/09/2010

Recruitment status

No longer recruiting

Registration date

07/10/2010

Overall study status

Completed

Last Edited

07/10/2010

Condition category

Nutritional, Metabolic, Endocrine

☐ 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

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)

Primary study design

Interventional

Study design

Randomised crossover feeding intervention study

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