

Effects of combining a plant stanol enriched yogurt drink and a low dose statin on markers for inflammation and endothelial function and serum lipoprotein concentrations

Submission date 19/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 01/09/2009	Condition category Other	☐ 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

NTR389

Study information

Scientific Title

Study objectives

Major null hypothesis, H0:

As compared with a plant stanol ester free diet, a stanol ester enriched diet does not change serum concentrations lipids and lipoproteins both when given alone or in combination with a low-dose (10 mg/day) simvastatin

Major alternative hypothesis, Ha:

As compared with a plant stanol ester free diet, a plant stanol ester enriched diet does improve serum concentrations lipids and lipoproteins both when given alone or in combination with a low-dose (10 mg/day) simvastatin

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Randomised double blind placebo controlled parallel group trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Endothelium, systemic inflammation, lipids, lipoproteins

Interventions

1. Control yogurt drink + placebo tablets
2. Control yogurt drink + simvastatin tablets (10 mg/day)
3. Plant stanol ester yogurt drink + placebo tablets
4. Plant stanol ester yogurt drink + simvastatin tablets (10 mg/day)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Serum lipid and lipoprotein concentrations.

Key secondary outcome(s)

Serum markers for endothelial function and low grade systemic inflammation.

Completion date

05/08/2005

Eligibility

Key inclusion criteria

1. Stable dietary habits
2. Men 55-70 years of age
3. Men 45-54 and women 55-70 years of age with at least one of the following criteria:
 - 3.1. Familial history of coronary heart disease (CHD) in first degree relatives (parent/brother/sister). Only CHD in male relatives below 55 years and in female relatives below 65 years is considered.
 - 3.2. Overweight as defined by body mass index (BMI) >25 (as calculated from weight and length) or abdominal obesity (waist circumference >102 cm for men, >88 cm for women)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Smoking
2. Active cardiovascular disease like congestive heart failure or recent (< 6 months) event (acute myocardial infarction, CVA)
3. Peripheral vascular disease
4. Familial hypercholesterolemia
5. Impairment of renal function, as evidenced by increased serum creatinine >150 mmol/l
6. Hepatic diseases as manifested by alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyltransferase (GGT), total bilirubin or alkaline phosphatase (ALP) >2 times the upper limit of normal
7. Severe medical conditions that might interfere with the study such as epilepsy, asthma, chronic obstructive pulmonary disease (COPD), inflammatory bowel diseases, and rheumatoid arthritis
8. Use of medication such as corticosteroids, diuretics or lipid lowering medication including statin use in the prior 2 months
9. Hypersensitivity to simvastatin or any excipient
10. Previous history of muscular toxicity with a statin or fibrate
11. Concomitant use of potent CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, human immunodeficiency virus [HIV] protease inhibitors, erythromycin, clarithromycin, telithromycin, nefazodone)
12. Unstable body weight (weight gain or loss >3 kg in the past three months)
13. Abnormal hematological profile
14. Abuse of drugs and/or alcohol

- 15. Pregnant or breastfeeding women
- 16. Use of sterol or stanol ester products within the previous 30 days
- 17. Participation in another study within 1 month prior to the screening visit
- 18. Having donated blood (as blood donor) within 1 month prior to the screening visit or planning to do so during the study

Date of first enrolment

25/01/2005

Date of final enrolment

05/08/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

Maastricht University

Maastricht

Netherlands

6200 MD

Sponsor information

Organisation

Nutrition and Toxicology Research Institute Maastricht (NUTRIM) (Netherlands)

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Industry

Funder Name

Mc Neil Consumer Nutritionals (Europe)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration