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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

Study design
Randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

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 5570 years of age
3. Men 4554 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