

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/09/2009	Condition category Other	<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

Contact name

Dr J. Plat

Contact details

Maastricht University
Nutrition and Toxicology Research Institute Maastricht (NUTRIM)
Departments of Human Biology
P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 3881309
J.Plat@HB.unimaas.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

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 measure

Serum lipid and lipoprotein concentrations.

Secondary outcome measures

Serum markers for endothelial function and low grade systemic inflammation.

Overall study start date

25/01/2005

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

Age group

Other

Sex

Both

Target number of participants

132

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)

Sponsor details

P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 3881476
m.grispen@nutrim.unimaas.nl

Sponsor type

Research organisation

ROR

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

Funder(s)**Funder type**

Industry

Funder Name

Mc Neil Consumer Nutritionals (Europe)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration