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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25058

Source
NTR

Brief title
N/A

Sponsors and support

Primary sponsor: Mc Neil Consumer Nutritionals Europe. 3-8 Carburton Street London WIW 5AJ

Intervention

Outcome measures

Primary outcome

Serum lipid and lipoprotein concentrations.

Secondary outcome

Serum markers for endothelial function and low grade systemic inflammation.

Study description

Background summary

N/A

Study objective

Major null hypotheses, 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 hypotheses, 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.

Study design

N/A

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

1. Stable dietary habits;

2. Men 55 –70 years of age;

3. Men 45 –54 and women over 55 -70 years of age with at least one of the following criteria :

a. 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;

b. Overweight as defined by BMI >25 (as calculated from weight and length) or abdominal obesity (waist circumference >102 cm for men, >88 cm for women).

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 ALT, AST, GGT, total billirubin or ALP > 2 times the upper limit of normal;

7. Severe medical conditions that might interfere with the study such as epilepsy, asthma, 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 (eg itraconazole, ketoconazole, 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2005
Enrollment:	132
Type:	Actual

Ethics review

Positive opinion

Date:	13-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL350
NTR-old	NTR389
Other	: N/A
ISRCTN	ISRCTN21530271

Study results

Summary results
N/A