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.

Gepubliceerd: 13-09-2005 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25058

Bron
NTR

Verkorte titel
N/A

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Serum lipid and lipoprotein concentrations.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	25-01-2005
Aantal proefpersonen:	132
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A