MRS AD Study.

Gepubliceerd: 13-03-2012 Laatst bijgewerkt: 18-08-2022

A 4 week intervention with the study product will affect MRS detectable brain metabolites related to phospholipid metabolism.

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

Samenvatting

ID

NL-OMON23328

Bron
Nationaal Trial Register

Verkorte titel
MRS AD study

Aandoening

Alzheimer¡¯s Disease

Ondersteuning

Primaire sponsor: Danone Research ¨C Centre for Specialised Nutrition
Overige ondersteuning: Danone Research ¨C Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The main 31P-MRS outcome parameters are the total level of Phosphomonoesters (PME), total level of Phosphodiesters (PDE), and the ratio between PME and PDE;
2. 1H-MRS outcome parameters: Absolute and relative brain tissue levels of several metabolites.

Toelichting onderzoek

Achtergrond van het onderzoek

In this trial the effect of intervention with a Medical Food on phospholipid metabolism in the brain will be compared with a control product in subjects with mild Alzheimer's disease dementia. The study is performed in 1 centre in the Netherlands.

Doel van het onderzoek

A 4 week intervention with the study product will affect MRS detectable brain metabolites related to phospholipid metabolism.

Onderzoeksopzet

Baseline (day 0);

Visit 2 (day 28).

Onderzoeksproduct en/of interventie

Duration of intervention: 4 weeks.

Intervention group:

All participants in the intervention group will receive daily 125 ml of Souvenaid®. Souvenaid® is a 125ml (125kcal) once-a-day drink that contains the specific nutrient combination FortasynTM Connect.

Control group:

All participants in the control group will receive daily 125 ml of a control product. The control product is iso-caloric, similar in flavour, appearance, and composition without FortasynTM Connect.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Main inclusion criteria:

1. Diagnosis of probable or possible AD with evidence of the pathophysiological process according to the recently revised criteria;

2. MMSE score ≥ 20;

3. MRI or CT scan within two years before baseline showing no evidence of any other potential cause of dementia other than AD;

4. Age ≥ 50 years;

5. Availability of responsible caregiver;

6. Written informed consent of patient and caregiver.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Main exclusion criteria:

1. Diagnosis of significant neurological and/or psychiatric disease other than AD;

2. History or expected need during the study of approved anti-AD medication;

3. Geriatric Depression Scale > 6 on 15-item scale;

4. Hachinski Ischemia Scale score > 5;

5. Use within two months prior to baseline of:

A. Omega-3 fatty acid containing supplements;

B. Oily fish (when consumed more than twice a week).

6. Alcohol or drug abuse in opinion of the investigator;

7. Contraindications to magnetic resonance imaging (MRI).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-03-2012
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	NL3195
NTR-old	NTR3346
Ander register	Danone : Alz.1.C/H
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Results published in 'Alzheimer's Research & Therapy', website: https://doi.org/10.1186/s13195-017-0286-2