MRS AD Study.

No registrations found.

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

Summary

ID

NL-OMON23328

Source
Nationaal Trial Register

Brief title
MRS AD study

Health condition

Alzheimer¡¯s Disease

Sponsors and support

Primary sponsor: Danone Research ¨C Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research ¨C Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Blood parameters: Nutritional blood parameters.

Study description

Background summary

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.

Study objective

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

Study design

Baseline (day 0);

Visit 2 (day 28).

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

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):	01-04-2012
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

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

Study results

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