Souvenir II.

No registrations found.

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

Summary

ID

NL-OMON23021

Source
Nationaal Trial Register

Brief title
Souvenir II

Health condition

Alzheimer’s Disease

Sponsors and support

Primary sponsor: Danone Research, Centre For Specialised Nutrition
Source(s) of monetary or material Support: Danone Research, Centre For Specialised Nutrition

Intervention

Outcome measures

Primary outcome

Memory performance (NTB) during 24 weeks of intervention.

Secondary outcome

Cognition (NTB), DAD, EEG (exploratory MEG in a subset of subjects), Nutritional blood parameters, tolerance and safety during 24 weeks of intervention.

Exploratory MEG in a subset of subjects.

Study description

Background summary

In this trial the efficacy of intervention with a Medical Food on memory performance will be compared with a control product in Patients with mild Alzheimer’s Disease. The study is performed in 28 centers in the Netherlands, Belgium, Germany, Spain and Italy.

Study objective

Dietary management of nutrient deficiencies with the medical food under study has a positive effect on memory performance in patients with mild Alzheimer’s Disease.

Study design

0, 12 and 24 weeks.

Intervention

1. Duration of intervention: 24 weeks;

2. Intervention group: All participants in the intervention group will receive daily 125 ml of Souvenaid®. Souvenaid® is a 125ml (125kcal) once-a-day milk-based drink. Souvenaid® contains FortasynTM Connect [a specific combination of nutrients];

3. 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

1. Diagnosis of probable AD according to the NINCDS-ADRDA criteria;

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

3. MMSE ≥ 20;

4. Age ≥ 50 years;

5. Written informed consent;

6. Availability of a responsible caregiver.

Exclusion criteria

1. Diagnosis of significant neurological disease other than AD;

2. Use within 3 months prior to baseline, or expected need during the study of approved anti-AD medication;

3. Geriatric Depression Scale> 4 on 15-item scale;

4. 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);

C. Alcohol or drug abuse in opinion of the investigator.

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):	01-09-2009
Enrollment:	226
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-09-2009
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	NL1863
NTR-old	NTR1975
Other	Danone Research – Centre for : Protocol Alz.1.C/D
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Scheltens et al. J Alzheimers Dis. 2012 31(1):225-36.
De Waal et al. PLoS ONE. 2014 9(1): e86558.