S-Connect.

No registrations found.

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

Summary

ID

NL-OMON24247

Source
Nationaal Trial Register

Brief title
S-Connect

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

Cognitive Performance (ADAS-cog) during 24 weeks of intervention.

Secondary outcome

1. ADCS-ADL;

2. Cognitive test battery;

3. CDR-SOB;

4. Nutritional blood parameters;

5. Tolerance and safety.

All during 24 weeks of intervention.

Study description

Background summary

In this trial the Efficacy of intervention with a Food on cognitive performance will be compared with a control product in Patients with Mild to Moderate Alzheimer's Disease using Alzheimer's Disease Medication.

Study objective

Intervention with the food under study has a positive effect on cognitive performance in patients with mild to moderate Alzheimer's Disease.

Study design

0, 12 and 24 weeks.

Intervention

Duration of intervention: 24 weeks.

Intervention group: all participants in the intervention group will receive daily 125 ml of Souvenaid®. Souvenaid(r) is a 125ml (125kcal) once-a-day multi-nutrient drink. Souvenaid® contains FortasynTM Connect [a specific combination of nutrients].

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. MMSE score 14-24;

3. Use of approved anti-AD medication on a stable dose for at least four months prior to baseline and anticipated stable use throughout the entire study period;

4. Age 50 years or older;

5. Availability of responsible caregiver;

6. Written informed consent of patient and caregiver.

Exclusion criteria

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

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

3. 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).

4. 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):	01-03-2009
Enrollment:	500
Type:	Actual

Ethics review

Positive opinion

Date:	23-02-2009
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	NL1603
NTR-old	NTR1683
Other	Danone Research – Centre for Specialised Nutrition : Protocol Number Alz.1.C/C
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
Shah et al., J Nutr Health Aging, 2011;15; Suppl 1:S30.