The use of a food for special medical purposes (product ID 4804/4805) in patients with early Alzheimer’s Disease.

No registrations found.

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

Summary

ID

NL-OMON22420

Source
Nationaal Trial Register

Brief title
Souvenir

Health condition

Alzheimer Disease

Sponsors and support

Primary sponsor: Numico Research B.V.
Source(s) of monetary or material Support: Numico Research B.V.

Intervention

Outcome measures

Primary outcome

Cognitive Performance at 12 weeks.

Secondary outcome

Cognitive Performance at other time points in study. Behaviour, functional abilities, Quality of Life and blood parameters. All outcome parameters will be evaluated using validated interviews and tests.

Study description

Background summary

The investigational test product is developed for the dietary management of Alzheimer's disease. Patients with early Alzheimer's Disease will be randomized in this parallel, double-blinded study to use the test product for an intervention period of 12 weeks (with a possible extension of another 12 weeks). Cognitive performance, behaviour, functional abilities, Quality of Life and blood parameters will be evaluated at regular intervals (weeks 3, 6, 12, 18, 24) throughout the intervention period. The patient's caregiver will support the patient during the study and during the visits and s/he will be interviewed as well.

Study objective

Dietary intervention using the food for special medical purposes in question to address specific nutrient deficiencies has a positive effect on cognitive performance in patients with early Alzheimer's Disease.

Study design

N/A

Intervention

Duration intervention: 12 weeks, with possible extension of 12 weeks.

Intervention group: all participants in the intervention group will receive daily 125 ml of a nutritional supplementation, containing particular nutrients that are expected to have a positive effect on cognitive performance in patients with early Alzheimer's Disease.

Control group: all participants in the control group will receive daily 125 ml of an isocaloric nutritional supplementation, without the nutrients that have been added to the active study product.

Contacts

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Eligibility criteria

Inclusion criteria

1. Out-patients, age >= 50 yrs;

2. Diagnosis of probable Alzheimer Disease according to the NINCDS-ADRDA criteria;

3. MRI or CT scan compatible with diagnosis of Alzheimer’s Disease within 2 yr prior to inclusion;

4. MMSE score between 20-26 (inclusive);

5. Hachinski Ischemia Scale Score =< 4;

6. No depressive symptoms (GDS =< 4);

7. Females are postmenopausal or surgically sterile;

8. Availability of caregiver;

9. Written informed consent from patient and caregiver.

Exclusion criteria

1. Vascular dementia;

2. History, or expected need during the study of cholinesterase-inhibitors or NMDA-receptor antagonists or medications with cholinergic or anticholinergic side effects;

3. Use of specific antidepressants, tranquilizers and lipid lowering medications if not on stable use for at least three months prior to baseline;

4. (Expected) Use of specific (doses of) nutritional supplements;

5. Presence of Down Syndrome;

6. Investigator’s uncertainty about the willingness or ability of the patient to comply with the protocol requirements;

7. Participation in any other studies involving investigational or marketed products concomitantly or within eight weeks prior to baseline;

8. Excessive alcohol intake or drug abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2006
Enrollment:	214
Type:	Actual

Ethics review

Positive opinion

Date:	20-06-2006
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	NL642
NTR-old	NTR702
Other	: Protocol Number 60.44
ISRCTN	ISRCTN72254645

Study results

Summary results
Efficacy of a medical food in mild Alzheimer’s disease: A randomized, controlled trial. Alzheimer’s & Dementia 6 (2010) 1–10.
Philip Scheltensa,*, Patrick J. G. H. Kamphuisb, Frans R. J. Verheyc, Marcel G. M. Olde Rikkertd, Richard J. Wurtmane, David Wilkinsonf, Jos W. R. Twiskg, Alexander Kurzh.

EFFICACY OF A MEDICAL FOOD ON COGNITION IN ALZHEIMER’S DISEASE: RESULTS FROM SECONDARY ANALYSES OF A RANDOMIZED, CONTROLLED TRIAL. J Nutr Health Aging. 2011 15(8):720-4
P.J.G.H. KAMPHUIS, F.R.J. VERHEY, M.G.M. OLDE RIKKERT, J.W.R. TWISK, S.H.N. SWINKELS, P. SCHELTENS

Effect of a medical food on Body Mass Index and activities of daily living in patients with Alzheimer’s disease: secondary analyses from a randomized, controlled trial. J Nutr Health Aging. 2011 15(8), 672-676.
P.J.G.H. kamphuis, F.R.J. verhey, M.G.M. Olde Rikkert, J.W.R. Twisk, S.H.N. Swinkels, P.

Scheltens.