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

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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.

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

Samenvatting

ID

NL-OMON22420

Bron
Nationaal Trial Register

Verkorte titel
Souvenir

Aandoening

Alzheimer Disease

Ondersteuning

Primaire sponsor: Numico Research B.V.
Overige ondersteuning: Numico Research B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cognitive Performance at 12 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Numico Research B.V.
PO Box 7005

Patrick Kamphuis
Wageningen 6700 CA
The Netherlands
+31 (0)317 467 800

Wetenschappelijk

Numico Research B.V.
PO Box 7005

Patrick Kamphuis
Wageningen 6700 CA
The Netherlands
+31 (0)317 467 800

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	30-06-2006
Aantal proefpersonen:	214
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-06-2006
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	NL642
NTR-old	NTR702
Ander register	: Protocol Number 60.44
ISRCTN	ISRCTN72254645

Resultaten

Samenvatting resultaten
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.