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The use of food for special medical purposes (product ID 4804/4805) in patients with early Alzheimer's disease

Submission date	Recruitment status	[ ] Prospectively registered
19/07/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/11/2013	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
60.44

Study information

Scientific Title

Added as of 28/07/09:
The use of a medical food (product ID 4804/4805) in patients with early Alzheimers Disease. A randomised, controlled, double-blind 12-week study on cognitive performance, with a 12-week extension

Acronym
SOUVENIR

Study objectives
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.

As of 28/07/09 this record was updated, All updates can be found under the the relevant field with the above update date. Please also note that Belgium, Germany, UK and USA were added to the countries of recruitment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 28/07/09:
VU Medical Centre, Amsterdam, Medisch Ethische Toetsingscommissie (METC) gave approval on the 18th of May 2006 (ref: 2005/035)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Alzheimer's disease

Interventions
Duration intervention: 12 weeks, with possible extension of 12 weeks.
Intervention group: all participants within the interventional group will receive 125 ml daily nutritional supplement that contains particular nutrients that are expected to have a positive effect on cognitive performance in patients with early Alzheimer's disease.
Control group: all participants within the control group will receive a daily 125 ml isocaloric nutritional supplement, without the nutrients that have been added to the active study product.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Cognitive performance at 12 weeks

Key secondary outcome(s)
Cognitive performance at other time points in study, behavioural, functional abilities, quality of life and blood parameters.
All outcome parameters will be evaluated using validated interviews and tests.

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Out-patients, age >= 50 years
2. Diagnosis of probable Alzheimer's disease according to the National Institute of Neurological and Communication Disorders and Stroke - Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria
3. Magnetic resonance imaging (MRI) or computerised tomography (CT) scan compatible with the diagnosis of Alzheimer's Disease within two years prior to inclusion
4. Mini-Mental Status Exam (MMSE) score between 20-26 (inclusive)
5. Hachinski Ischemia Scale score =<4
6. No depressive symptoms (Geriatric Depression Scale [GDS] =<11)
7. Females that are postmenopausal or surgically sterile
8. Availability of caregiver
9. Written informed consent from patient and caregiver

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Vascular dementia
2. History, or expected need during the study of cholinesterase-inhibitors or N-methyl d-aspartate (NMDA)-receptor antagonists or medications with cholinergic or anticholinergic side effects
3. Use of specific antidepressants, tranquilizers or 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's 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

Date of first enrolment
30/06/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
United Kingdom

Belgium

Germany

Netherlands

United States of America

Study participating centre
Numico Research B.V.
Wageningen
Netherlands
6700 CA

Sponsor information

Organisation
Numico Research B.V. (Netherlands)

ROR
https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

Funder Name
Numico Research B.V. (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No