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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/07/2006		☐ 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

Contact name

Dr Patrick Kamphuis

Contact details

Numico Research B.V.
PO Box 7005
Wageningen
Netherlands
6700 CA
+31 (0)317 467 800
Patrick.Kamphuis@Numico-Research.nl

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)

Study design

Randomised controlled trial

Primary study design

Interventional

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

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 ad	ded Peer review	ed? Patient-facing?
Results article	results	01/01/2010	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2	.025 No	Yes