

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

Submission date
19/07/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
19/07/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
15/11/2013

Condition category
Nervous System Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request patient information sheet

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 measure

Cognitive performance at 12 weeks

Secondary outcome measures

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.

Overall study start date

30/06/2006

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

Age group

Senior

Sex

Both

Target number of participants

214

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**

Belgium

Germany

Netherlands

United Kingdom

United States of America

Study participating centre

Numico Research B.V.

Wageningen

Netherlands

6700 CA

Sponsor information

Organisation

Numico Research B.V. (Netherlands)

Sponsor details

P.O. Box 7005
Wageningen
Netherlands
6700 CA

Sponsor type

Industry

ROR

<https://ror.org/00aj77a24>

Funder(s)

Funder type

Industry

Funder Name

Numico Research B.V. (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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