ISRCTN72254645 https://doi.org/10.1186/ISRCTN72254645

# 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

**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
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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 |