A study exploring the effect of a nutritional intervention on

brain activity in patients with mild cognitive impairment or

mild dementia due to Alzheimer's disease

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24193

Source
Nationaal Trial Register

Brief title
NL-ENIGMA

Health condition

Alzheimer's disease, Nutrition, Nutritional intervention, Souvenaid, FDG-PET, Glucose metabolism

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: The Netherlands Organisation for Scientific Research (NWO) within the Food, Cognition and Behaviour initiative.

Intervention

Outcome measures

Primary outcome

Change in primary outcome 15-04-2016:
Exploring the effect of 24-week intervention with Souvenaid on cerebral glucose metabolism, assessed with 18F-FDG-PET imaging using quantification of regional cerebral metabolism rate for glucose (CMRglc):

1. Absolute quantitative values using arterial sampling and kinetic analysis;

2. Relative semi-quantitative standardized uptake value ratios (SUVr) with a normalisation region (cerebellum and pons) at a predefined standard uptake time interval of 45-60 minutes post injection.

Secondary outcome

Change in secondary outcome 15-04-2016:
Additional exploratory parameters
• Cerebral glucose metabolism as assessed with 18F-FDG-PET imaging using quantification of 18F-FDG uptake by semi-quantitative standardized uptake values (SUV) and SUVr, the latter using a normalisation region (cerebellum and pons), using different uptake time intervals

• MRI biomarkers:
- 3D T1 weighted MRI: atrophy rates in different brain regions
- rs-fMRI: mean synchronisation likelihood of the whole brain
- DTI: mean fractional anisotropy of voxels in white matter skeleton
- DTI-based structural brain networks
- ASL measures: mean cerebral blood flow in Alzheimer ROIs
- q-flow: Volume of blood flow to the brain

• Blood biomarkers:
- vitamin E
- homocysteine (Hcy)
- fatty acid profile in erythrocytes
- other markers like nutritional parameters might be analysed

• CSF markers (optional):
- Aβ1-40 and 1-42, total tau (tau) and tau phosphorylated at threonine-181 (ptau) will exploratory be analysed
- Other markers like nutritional CSF parameters might be analysed

• Cognition:
- RAVLT immediate and delayed recall and recognition test
- TMT-A and TMT-B

Study description

Background summary

The NL-ENIGMA study is a single-centre study exploring the effect of nutritional intervention Souvenaid on brain glucose metabolism using 18F-FDG-PET with arterial sampling. Forty patients with mild cognitive impairment or mild dementia due to Alzheimer's disease will complete the study. The intervention consists of daily intake of Souvenaid or placebo (randomisation 1:1, double-blind). Patients undergo 18F-FDG-PET and MRI assessment, blood sampling, cognitive testing and optional a lumbar puncture at baseline and after 24 weeks.

Study objective

24-week intervention with Souvenaid (containing Fortasyn Connect) positively affects glucose metabolism in patients with mild cognitive impairment or mild dementia due to Alzheimer's disease.

Study design

screening

baseline

12-weeks visit

24-weeks visit

Intervention

Medical food Souvenaid (containing Fortasyn Connect) or placebo for an intervention period of 24 weeks

Contacts

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Eligibility criteria

Inclusion criteria

Change in inclusion criteria 15-04-2016:
• Subjects diagnosed with MCI due to AD according to the criteria from the National Institute on Aging and the Alzheimer’s Association (NIA-AA) (Albert et al., Alzheimer's & Dementia. 2011;7:270-279) or diagnosed as having mild dementia due to AD according to the NIA-AA criteria (McKhann et al., Alzheimer’s & Dementia. 2011; 7:263–269).

• Evidence for a positive AD biomarker: positive amyloid PET-scan OR ratio CSF total tau / amyloid-beta 1-42 (Aβ1-42) > 0.52 (Duits et al., in press)

• Age 50–85 years (inclusive)

• MMSE ≥ 20

• Written informed consent from subject

• Available reliable study partner (informant) who agrees to monitor administration of study product

Exclusion criteria

• Diagnosis of significant neurological and / or psychiatric disease other than AD, including vascular dementia according to NINDS-AIREN criteria, cerebral tumour, Huntington's disease, Parkinson's disease, normal pressure hydrocephalus (NPH), seizures, delirium, schizophrenia, major depression and other entities relevant for brain function.

• Diagnosis of diabetes or use of anti-diabetic medication. Non-fastening blood glucose concentration ≥ 10.0 mmol/l at screening is an exclusion criterion, unless blood glucose concentration is < 7.0 mmol/l when measurement is repeated when patient is in fasting state.

• Diagnosis of stroke, intracranial haemorrhage, mass lesion, NPH or white matter hyperintensities according to Fazekas scale 3 on MRI. MRI must not be older than one year.

• Use within three months prior to baseline, or expected need during the study, of donepezil, rivastigmine, galantamine and / or memantine

• Contraindications to PET or MRI (e.g., claustrophobia, pacemaker, metallic implants, current use of anticoagulants) • Alcohol or drug abuse

• Use within three months prior to baseline of Souvenaid

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	40
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-08-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44286
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4493
NTR-old	NTR4718

Register	ID
CCMO	NL49949.029.14
OMON	NL-OMON44286

Study results

Summary results

Scheltens NME, Kuyper IS, Boellaard R, Barkhof F, Teunissen CE, Broersen LM, Lansbergen MM, Van der Flier WM, Van Berckel BNM, Scheltens Ph. Design of the NL-ENIGMA study: Exploring the effect of Souvenaid on cerebral glucose metabolism in early Alzheimer's disease. Alzheimers Dement: TR & CI, 2016 (223-240).

Scheltens NME & Briels CT, Yacub M, Barkhof F, Boellaard R, Van der Flier WM, Schwarte LA, Teunissen CE, Attali A, Broersen LM, Van Berckel BNM & Scheltens P. Exploring effects of Souvenaid on cerebral glucose metabolism in Alzheimer’s disease. Alzheimers Dement: TR & CI, 2019 (492-500).