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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24193

Bron
Nationaal Trial Register

Verkorte titel
NL-ENIGMA

Aandoening

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

Ondersteuning

Primaire sponsor: VU University Medical Center

Overige ondersteuning: The Netherlands Organisation for Scientific Research (NWO) within the Food, Cognition and Behaviour initiative.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

screening

baseline

12-weeks visit

24-weeks visit

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44286
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4493
NTR-old	NTR4718
CCMO	NL49949.029.14
OMON	NL-OMON44286

Resultaten

Samenvatting resultaten
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).