LipiDiDiet Trial.

Gepubliceerd: 09-03-2009 Laatst bijgewerkt: 13-12-2022

Dietary management of nutrient deficiencies with the medical food under study has a positive effect on cognitive performance in patients with prodromal Alzheimer's Disease.

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

Samenvatting

ID

NL-OMON21572

Bron
Nationaal Trial Register

Verkorte titel
LipiDiDiet Trial

Aandoening

Prodromal Alzheimer's Disease

Ondersteuning

Primaire sponsor: The European LipiDiDiet Consortium
Overige ondersteuning: Main funding: European Community under the Seventh Framework Programme
During the conduct of the trial additional funding was acquired for parts of the trial, parts of the data analysis, and/or one or more of the individual scientists involved in the trial:
* European Research Council (grant 804371)
* Academy of Finland (grants 317465, 287490)
* Danone Nutricia Research (as part of the LipiDiDiet Consortium)
* EU Joint Programme - Neurodegenerative Disease Research (JPND) (MIND-AD, EURO-FINGERS grants)
* Kuopio University Hospital, Finland (EVO/VTR grant)
* Alzheimerfonden Sweden
* Swedish Research Council
* Stockholm City Council (ALF grant)
* Center for Innovative Medicine (CIMED), Karolinska Institute, Sweden

* Stiftelsen Stockholms sjukhem, Sweden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cognitive Performance during 24 months of intervention as measured by a modified version of the NTB (Harrison et al).

Toelichting onderzoek

Achtergrond van het onderzoek

In this trial the efficacy of intervention with a Medical Food on

cognitive performance will be compared with a control product in

Patients with prodromal Alzheimer’s Disease. The study is performed

in 11 centers in Finland (1x), Sweden (1x), the Netherlands (3x) and

Germany (6x)

Doel van het onderzoek

Dietary management of nutrient deficiencies with the medical food under study has a positive effect on cognitive performance in patients with prodromal Alzheimer's Disease.

Onderzoeksopzet

Screening, baseline, months 3, 6, 9, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72, 78, 84, 90, 96

Onderzoeksproduct en/of interventie

Duration of intervention: 24 months

Intervention group: all participants in the intervention group will receive daily 125 ml of Souvenaid®. Souvenaid® is a 125ml (125kcal) once-a-day multi-nutrient drink. Souvenaid® contains FortasynTM Connect [a specific combination of nutrients].

Control group: All participants in the control group will receive daily 125 ml of a control

product. The control product is iso-caloric, similar in flavour, appearance, and composition without FortasynTM Connect.

Contactpersonen

Publiek

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Wetenschappelijk

-
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Prodromal AD as defined by episodic memory disorder and evidence for underlying AD pathology (Dubois et al 2007);

2. Age 55 - 85 years;

3. MMSE >= 20;

4. Written informed consent;

5. Availability of a responsible caregiver.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Dementia according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV);

2. Use of omega-3 preparations;

3. Historical use of AD medication;

4. Alcohol or drug abuse;

5. A concomitant serious disease;

6. Major depressive disorders (DSM-IV);

7. Intake of specific (doses) of nutritional supplements;

8. Participation in any other clinical trial in the last 30 days;

9. Subjects with MRI scan consistent with a diagnosis of stroke, intracranial bleeding, mass lesion or NPH.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2009

Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
LipiDiDiet is an ongoing study. The LipiDiDiet consortium is open to all requests from external researchers for data collected in the trial. The study protocol is publicly available online at http://lipididiet.eu/fileadmin/lipididiet/publications/LipiDiDietStudyProtocol.pdf. Requesters will be asked to submit a study protocol, including the research question, planned analysis, and data required. The LipiDiDiet Trial Steering Committee will evaluate this plan (i.e., relevance of the research question, suitability of the data, quality of the proposed analysis, compliance with GDPR legislation, planned or ongoing LipiDiDiet analysis, and other matters) on a case-by-case basis and provide the data or reject the request. Shared data will encompass the data dictionary and de-identified participant data only. Any analysis will be conducted in collaboration with and on behalf of the LipiDiDiet consortium. Access is subject to the LipiDiDiet legal framework. An access agreement will be prepared and signed by both parties.

Ethische beoordeling

Positief advies

Datum:	09-03-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1620
NTR-old	NTR1705
Ander register	The European LipiDiDiet Consortium : Protocol Number 1/090129
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

* Soininen H, et al. Lancet Neurol. 2017;16:965-75 [PMID: 29097166]
* Van Oudenhoven FM, et al. BMC Med Res Methodol. 2019;19:163 [PMID: 31345172]
* Hendrix SB, et al. The Journal of Prevention of Alzheimer's Disease, 2019:1-5 [PMID: 31686094]
* Soininen H, et al. Alzheimer's Dement. 2021;17:29-40 [PMID: 32920957]
* Van Oudenhoven FM, et al. Alz Res Therapy. 2021;13:63 [PMID: 33752738]
* Rosenberg A, et al. Alz Res Therapy. 2021;13:64 [PMID: 33766132]