LipiDiDiet Trial.

No registrations found.

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

Summary

ID

NL-OMON21572

Source
NTR

Brief title
LipiDiDiet Trial

Health condition

Prodromal Alzheimer's Disease

Sponsors and support

Primary sponsor: The European LipiDiDiet Consortium
Source(s) of monetary or material Support: 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

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Progression to dementia
- Cognitive performance as measured by modified NTB cognitive domains
- Functional abilities / clinical global impression as measured by CDR Sum of Boxes
- Plasma biomarkers
- Atrophy rates on MRIs
- Nutritional (blood) parameters
- Tolerance and safety

All during 24 months of intervention.

Study description

Background summary

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)

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

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):	01-03-2009
Enrollment:	300
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

Ethics review

Positive opinion

Date:	09-03-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results

* 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]