A Magnetic Resonance Spectroscopy (MRS) study to explore the effects of a medical food on brain metabolites in patients with mild Alzheimer's Disease dementia(AD)

Published: 18-01-2012
Last updated: 28-04-2024

To explore the effects of the test product compared to the control product on brain phospholipid metabolism in mild AD patients using 31P-MRS. To explore the effects of the test product compared to the control product on the level of brain...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON39865

Source
ToetsingOnline

Brief title
MRS AD study

Condition

- Neurological disorders NEC

Synonym
Alzheimer's Disease, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Bedrijf Danone Research

Intervention

Keyword: 1H-MRS and 31P-MRS, Alzheimer's Disease, brain metabolites, medical food

Outcome measures

Primary outcome

31P-MRS outcome parameters

- The main outcome parameters are the total level of Phosphomonoesters (PME),

total level of Phosphodiesters (PDE), and the ratio between PME and PDE. Other

- Other 31P-MRS outcome parameters are the absolute and relative brain tissue

levels of Phosphoethanolamine (PEtn), Phosphocholine (PCho),

Glycerophosphoethanolamine (GPEtn), and Glycerophosphocholine(GPCho).

2) 1H-MRS outcome parameters: Absolute and relative brain tissue levels of

Choline (Cho), Creatine (Cr), Phosphocreatine (PCr), N-Acetyl-Apartate (NAA),

Myo-inositol.

3) Blood parameters: Fatty acid profile in erythrocyte membrane, fatty acid

profile in plasma, Choline, Homocysteine, Vitamin E, Uridine, and optionally,

plasma phospholipids.

Secondary outcome

n/a

Study description

Background summary

Growing evidence is available on the safety and efficacy of a new nutritional product for the dietary management of Alzheimer's Disease (AD). However, the question that remains to be addressed is to what extent the active nutrients of this nutritional product cross the blood brain barrier and are present in te brain. In the current study, MRS assessments are used to examine whether the nutritional product affects the levels of brain metabolites that are associated with AD.

Study objective

To explore the effects of the test product compared to the control product on brain phospholipid metabolism in mild AD patients using 31P-MRS.
To explore the effects of the test product compared to the control product on the level of brain metabolites related to neural integrity in mild AD patients using 1H-MRS.
To explore the effects of the test product compared to the control product on blood parameters in mild AD patients.

Study design

The design is a randomised controlled dubbelblind parallel-group single centre study. The study will be conducted in 8 weeks, of which maximum 2 weeks screening period, 4 weeks intervention and 2 weeks follow up. The outcome parameters will be measured just prior to and at the end of the intervention period.

Intervention

The intervention, the study product, is a 125ml (125kcal) multi-nutrient drink. It should be taken once every day as addition to the daily diet. The product will be presented in two flavors, strawberry and vanilla.

Study burden and risks

Every subject will visit the hospital three times, for screening, baseline and after 4 weeks. During the screening, a short neuropsychological test will be performed and a questionnaire on depression will be taken. During the baseline and week 4 visit, a blood sample will be taken, a short physical examination will be conducted and the MRS and MRI measurements will be done (1.5 hours in total). The subject will be given a diary in which compliance with the study product should be written every day. This diary will also be used by the subject (or caregiver) to document exactly what the subject has eaten and drunk prior to the hospital visit, for the baseline and week 4 visit. On these days, the subject will need to follow restrictions on food intake (low in choline).
The subjects are not allowed to use medication for AD during the study.

The general risk for the subjects is considered to be low.

Contacts

Public
Nutricia Research

Uppsalalaan 12 12
Utrecht 3584 CT
NL
Scientific
Nutricia Research

Uppsalalaan 12 12
Utrecht 3584 CT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Diagnosis of probable or possible AD dementia
-MMSE score >= 20
-Age >= 50 years
-Written informed consent of patient and caregiver

Exclusion criteria

-Diagnosis of significant neurological and/or psychiatric disease other than AD
-Use within 3 months prior to baseline, or expected need during the study of donepezil, rivastigmine, galantamine, and/or memantine
-Geriatric Depression Scale > 6 on 15-item scale
-Hachinski Ischemia Scale score > 5
-Use within two months prior to baseline of: omega-3 fatty acid containing supplements, oily fish (when consumed more than twice a week)
-Use within one month prior to baseline of: atropine, scopolamine, tolterodine, hyoscyamine, biperiden, benztropine, trihexyphenidyl, oxybutynin, antipsychotics, vitamins B, C and/ or E > 200% RDI, high energy and/ or high protein nutritional supplements/medical foods, other investigational products
-Investigator*s uncertainty about willingness, ability, or medical status of patient to comply with protocol requirements

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	18-01-2012

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-06-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-10-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-02-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL37397.091.11