LipAD study: A proof of concept study on Postprandial lipid profiles and Alzheimer*s disease

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In this study we aim to compare postprandial chylomicron/lipid responses in Alzheimer patients and cognitively healthy people and to determine to what extend produced chylomicrons are loaded with Abeta.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON47842

Source
ToetsingOnline

Brief title
LipAD study

Condition

- Other condition

Synonym
Alzheimer's Disease

Health condition

cognitieve aandoening (dementie)

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Research (voormalig DLO)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Alzheimer's Disease, chylomicrons, fat challenge, postprandial responses

Outcome measures

Primary outcome

Plasma chylomicron profiles and chylomicron-related proteins, such as ApoE and

Abeta.

Secondary outcome

ApoE phenotype will be determined by an APOE genotyping method based on Real

Time PCR. This phenotype will not change and will therefore be determined only

at baseline and not postprandial.

Study description

Background summary

The prevalence of Alzheimer disease (AD) and cognitive decline increases dramatically. High-fat diets seem to increase the risk of getting AD. High fat meals are taken up by the intestine and their triglyceride content enter the circulation via chylomicrons. ApoE is highly present in these chylomicrons and carriers of a specific ApoE phenotype (like E4) have an increased risk for AD. The intestine and chylomicrons may therefore play a role in AD. The presence of Abeta protein also plays a crucial role in AD, but the origin of this Abeta is largely not known. Abeta and their precursor proteins are present in intestinal cells. We hypothesise that chylomicrons may serve as a vehicle for Abeta produced in intestinal epithelial cells and thereby may contribute to Abeta deposition in the brain.

Study objective

In this study we aim to compare postprandial chylomicron/lipid responses in

Alzheimer patients and cognitively healthy people and to determine to what extend produced chylomicrons are loaded with Abeta.

Study design

This study is an observational proof-of-concept study, in which postprandial differences in chylomicron responses between Alzheimer patients (n=15) and cognitively healthy subjects (n=15) will be explored. Each subject will visit the research facility once. Subjects will consume a low fat evening meal prior to the test day. On the test day, all subjects will consume a light breakfast at home (tea and biscuit). Thereafter, they will arrive by taxi to the research centre, we will insert a cannula and a baseline (t=0) blood sample will be collected. Participants will thereafter consume a high-fat shake and postprandial blood samples will be collected from the cannula at 1, 2, 4 and 6 hours after consumption of the shake. Participants will be offered a meal and will be brought home via a taxi service at the end of the study day.

Study burden and risks

In this study we will explore the potential role of chylomicron/lipid metabolism in AD. Therefore, it is essential to include (mildly) AD patients in our study. This study is group-related, non-therapeutic research with potentially partly mental incompetent participants. AD patients in our study are diagnosed with mild dementia and therefore mentally capable of signing a consent form. However, in order to avoid unwanted participation, we will obtain additional consent from the patients* caregiver. All study procedures will a second time be explained at the study day and study procedures will not continue if the subject shows signs of resistance. All items in the high-fat shake can be bought in the supermarket. Consumption of high amounts of fat may cause some gastro-intestinal discomfort in rare cases. Blood sampling will be performed via a cannula and the insertion can be painful and may cause a bruise. The amount of blood that is drawn from participants is relatively small (5 times 10-12ml = 50-60 ml in total over 6 hours) and is therefore within acceptable limits. If needed for the AD patients, the caregiver can be present during the study for support.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age > 65years old
Specific inclusion criteria for Alzheimer patients:
- A diagnosis of probable Alzheimer*s disease according to the NIA-AA guidelines, CDR (clinical dementia rating) 1 (mild dementia), established as part of normal patient care at the multidisciplinary Radboudumc memory clinic
- Presence of a caregiver (spouse, child).
- Able to provide written consent (consent will also be obtained from the caregiver).
Specific inclusion criteria for healthy controls:
- Absence of subjective or objective memory impairment, MOCA score >26.

Exclusion criteria

- Any digestive tract disorder that is expected to interfere with this study (e.g. (partial) gastric resection, (hemi)colectomy, Crohn*s disease, ulcerative colitis, colon cancer)
- Use of lipid lowering medication
- Use of antacids
- Dyslipidaemia
- Known allergy for any of the food components used in the study (milk, cream, sugars)
- Diabetic patients (Type I and II)
- Blood clotting disorders

- Drug abuse
- Current smokers
- Participation in other clinical trials in the past three months
- Behavioural disturbances associated with dementia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-01-2019
Application type:	First submission
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	NL61616.091.18