Challenge study: The efficacy of fish oil supplementation on cognitive performance in MCI patients and the influence of the APOE-epsilon4 allele.

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To study the short term effects of a pharmacological dose of fish oil on cognitive performance and on cerebral blood flow. Furthermore, we want to investigate whether carriers of the APOE*4 allele respond differently to fish oil treatment compared…

Ethical review	Approved WMO
Status	Pending
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON32051

Source
ToetsingOnline

Brief title
fish oil and cognitive performance in MCI patients

Condition

- Dementia and amnestic conditions

Synonym
cognitive decline

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: Zorg Onderzoek Nederland (ZonMw)

Intervention

Keyword: APOE-epsilon4, cognitive performance, fish oil, MCI

Outcome measures

Primary outcome

Cognitive performance as assessed by sensitive cognitive tests measuring

reaction time, visual memory and attention.

Secondary outcome

Cerebral blood flow will be measured by Trans-cranial Doppler.

Study description

Background summary

During the last years there has been growing interest in the hypothesis that high intake of fish and marine n-3 polyunsaturated fatty acids (PUFAs) might play a protective role against age-related loss of cognitive function. Several mechanisms that may underlie this relationship have been postulated. N-3 PUFAs may reduce oxidative stress, have an anti-inflammatory action and have been linked with aspects of neuron function, including neurotransmission, membrane fluidity, ion channel and enzyme regulation and gene expression. Furthermore, there are indications that individuals carrying the APOE-*4 allele respond differently to n-3 PUFA supplementation. Our hypothesis is that subjects receiving fish oil supplements will perform better on cognitive performance tests. Furthermore, we hypothesize that this might be caused by an improved cerebral perfusion. Next to that we also investigate the influence of APOE4 status on these outcomes measures.

Study objective

To study the short term effects of a pharmacological dose of fish oil on cognitive performance and on cerebral blood flow. Furthermore, we want to investigate whether carriers of the APOE*4 allele respond differently to fish oil treatment compared to non-carriers.

Study design

Randomized, placebo-controlled, double-blind trial where subjects will be supplemented with fish oil during 4 weeks.

Intervention

One group (n=20) receives capsules containing an amount of 3g EPA-DHA daily and the other group (n=20) receives placebo capsules.

Study burden and risks

To be able to enter the study, participants need to fill out a short questionnaire with some questions regarding diet and lifestyle and a blood sample to determine APOE4 status will be collected. When an individual is eligible for participation baseline measurements will be performed. These consist of a battery of neuropsychological tests, which takes 30 minutes to be performed. Next to that cerebral blood flow will be measured using Trans-cranial Doppler. This measurement is safe and non-invasive, but a possible burden for the subjects is that this measurement takes 1.5 hours. Also a blood sample will be collected to determine n-3 fatty acid status and for isolation of peripheral blood mononuclear cells (PBMC). The baseline measurements will be repeated at the end of the study which is after 4 weeks. During the 4-week intervention participants will consume 9 capsules a day, preceded by a 1-week run-in period with the purpose to get used to consuming the capsules. Participants will keep a diary where they keep track of missed capsules, adverse events and other disease or medicine related events.
To summarize the burden for the participants: blood sample: 3x; site visits: 3x; questionnaire: 1x; neuropsychological tests: 2x; Trans-cranial Doppler: 2x; consuming capsules: 5 weeks (including run-in).

Contacts

Public
Wageningen Universiteit

Bomenweg 4
6703 HD Wageningen
Nederland
Scientific
Wageningen Universiteit

Bomenweg 4
6703 HD Wageningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Men and women
- Diagnosed as having amnestic MCI: based on specific memory disturbances (cut-off of 1 sd, single or multiple domain amnestic MCI)
- Informed consent signed

Exclusion criteria

- Current or recent (<4 weeks) use of fish oil supplements
- Consumption of fish more than 2 times/week
- Current use of dementia (Alzheimer) medication
- Current use of Acenocoumarol or other anti-thrombotic drugs
- Use of more than 4 glasses of alcohol per day
- Unable to participate as judged by the responsible medical physician
- Allergy to fish(oil)
- Swallowing problems
- Participation in another clinical trial less than 2 months before the start of the trial or at the same time

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

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	NL22810.091.08