The effect of algae oil supplements on functional immune response and bioavailability of lipids in blood, a pilot study

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The primary objective is to estimate functional immune response in isolated peripheral blood mononuclear cells (PBMCs; ratio of pro-inflammatory; i.e. PGE2, IL-1β, IL-6, IL-8, IFN*, TNFα, CCL2 and CCL5, and anti-inflammatory markers; i.e.,...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56896

Source
ToetsingOnline

Brief title
ALG study

Condition

- Other condition

Synonym
Bioavailability of omega-3, fatty acid absorption in blood, immune function, Immune response

Health condition

Immuun functie, opname van omega-3 vetzuren

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support:
Danone;Fermentalg;Micoalgas;TKI,Fermentalg,Micoalgas,Nutricia

Intervention

Keyword: DHA, EPA, Immune function, supplements

Outcome measures

Primary outcome

The primary study parameter is the functional immune response (ratio pro- and anti-inflammatory markers) measured in isolated PBMCs, collected at 0 hours (baseline), 4 hours, and 8 hours after consumption of the omega-3-rich supplements, and after 1-week exposure to the supplements.

Secondary outcome

The secondary study parameters are the DHA levels in blood and fatty acid levels in plasma and PBMCs, taken before and after the consumption of omega-3-rich supplements.

Study description

Background summary

During aging the immune system is weakened, increasing the vulnerability and severity of infectious diseases and the incidence of cancer and low-grade inflammation in elderly people. Adequate intake of Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acids is crucial for a properly functioning immune system, healthy brain development, and preventing conditions such as cardiovascular diseases. Unfortunately, the intake of EPA and DHA through diet remains below the recommended levels for certain target groups, such as the elderly, vegans and vegetarians. This leads to an increasing demand

for omega-3 fatty acid supplements. Due to sustainability reasons and evolving lifestyle trends, consumers often seek omega-3 products not derived from fish, creating a need for sustainable alternatives. The use of omega-3 fatty acids from microalgae is therefore an attractive alternative. However, little is known about how omega-3 fatty acids from algae oil supplements affect immune responses compared to fish oil supplements.

Study objective

The primary objective is to estimate functional immune response in isolated peripheral blood mononuclear cells (PBMCs; ratio of pro-inflammatory; i.e. PGE2, IL-1β, IL-6, IL-8, IFN*, TNFα, CCL2 and CCL5, and anti-inflammatory markers; i.e., IL-4 and IL-10) 0, 4, 8 hours, and 1 week after consumption of two different oil supplements and a fish oil supplement (control) in healthy elderly adults. The secondary objectives are 1) to estimate the postprandial DHA bioavailability in blood, and the ratio with triglycerides, after consumption of two different oil supplements and a fish oil supplement (control) in healthy elderly adults, and 2) to estimate fatty acid levels in plasma, and PBMCs at baseline and after 1-week consumption of two different oil supplements and a fish oil supplement (control) in healthy elderly adults. Tertiary objectives include 1) to estimate the postprandial EPA bioavailability in blood after consumption of two different oil supplements and a fish oil supplement (control) in healthy elderly adults, 2) to estimate oxylipin levels in plasma at 0, 4, 8 hours, and after 1 week after consumption of two different oil supplement and a fish oil supplement (control) in healthy elderly adults, 3) to estimate the ratio of postprandial pro- and anti-inflammatory markers in blood plasma (Pro-inflammatory; PGE2, IL-1β, IL-6, IL-8,IFN*, TNFα, CCL2 and CCL5, anti-inflammatory; IL-4 and IL-10) 0, 4, 8 hours and after 1 week after consumption of two different oil supplements and a fish oil supplement (control) in healthy elderly adults, 4) to estimate gastrointestinal symptoms (gastric acid, nausea, diarrhea, abdominal pain, flatulence, bloating), and short-term well-being/mood before and 4 hours, 8 hours, and 1-week after consumption of two different oil supplements and a fish oil supplement (control) in healthy elderly adults, and 5) estimate fatty acid levels in cell membranes of erythrocytes at baseline and after 1-week consumption of two different oil supplements and a fish oil supplement (control) in healthy elderly adults.

Study design

The study is a randomized, crossover, double-blind, controlled study.

Intervention

During each postprandial test day, the subjects receive one of the 3 omega-3-rich supplements (one of 2 types of algae oil supplements or a fish oil

supplement control) in capsule form (6 capsules per test day), in a randomized order. After each postprandial test day, the study subjects take 6 capsules per day of the same supplement for one week. After each treatment there will be a wash-out period of 2 weeks.

Study burden and risks

There are minor risks for the participants in this study. There are no direct benefits for the participants. In this research, we include healthy subjects based on the research criteria and a health questionnaire. The total amount of blood taken (678 ml) is spread over a minimum of seven weeks, and individuals with anemia are excluded. Therefore, blood collection is not expected to pose any issues. Participants involved in the study will invest approximately 34 hours in the research.

Contacts

Public
Wageningen Universiteit

Bornse Weilanden 9
Wageningen 6708WG
NL
Scientific
Wageningen Universiteit

Bornse Weilanden 9
Wageningen 6708WG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Apparently healthy men and women;
- Age >= 50 years
- Body mass index (BMI) >=18.5 and <=30 kg/m2;
- Having veins suitable for blood sampling via a catheter (judged by study nurse/ medical doctor);
- Willing to refrain from fish, fish oil, and products with added omega-3 starting from one 2 weeks prior to first postprandial test day.
- Willing to keep a stable dietary pattern throughout the study

Exclusion criteria

- Having a disease that may interfere with the outcomes of this study, such as a known metabolic, gastrointestinal, inflammatory or chronic disease (such as anaemia, diabetes, hepatitis, cardiovascular disease), as judged by the medical investigator;
- Having a history of medical or surgical events that may significantly affect the study outcome, including: Inflammatory bowel disease, hepatitis, pancreatitis, ulcers, gastrointestinal or rectal bleeding; major gastrointestinal tract surgery such as gastrectomy, gastroenterostomy, or bowel resection; known or suspected gastrointestinal disorders, colon or GI tract cancer;
- Use of medication that may interfere with the study outcomes, including gastric acid in-hibitors or laxatives, as judged by the medical supervisor.
- Anaemia (Haemoglobin (Hb) values <7.5 mmol/L for women and <8.5 mmol/L for men), as assessed by finger prick blood during screening visit;
- Having swallowing problems with capsules;
- Allergic for fish or shellfish;
- Recent blood donation (<1 month prior to test day 1 of the study) or not willing to stop donation during and 1 month after the study;
- Average alcohol intake >21 (women) or >28 (men) glasses of alcoholic beverages per week;
- Reported weight loss or weight gain of more than 3 kg in the month prior to pre-study screening, or intention to lose weight during the study period;
- Reported to follow or having planned a slimming or medically prescribed diet;
- Use of drugs;
- Current smokers, or stopped smoking in the last 3 months before study start;
- Insufficient proficiency in Dutch to understand information brochure and questionnaires;
- Participation in any clinical trial including blood sampling and/or administration of sub-stances up to 30 days before test day 1 of this study and during the study period;

- Being an employee of the department Food, Health & Consumer Research or Food Quality and Design of Wageningen Food & Biobased Research.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2024
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO Date:	29-07-2024
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	NL85977.091.23