Bioavailability of omega-3 fatty acids from fish oil supplements

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To compare the plasma concentration versus time profiles and postprandial bioavailability of DHA and EPA after a nutritionally relevant oral dose of 1.1 gram (expressed as DHA + EPA) administered as either CCx gelatin-based soft chews (emulsified)...

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

Summary

ID

NL-OMON57096

Source
ToetsingOnline

Brief title
Ocean's O3

Condition

- Other condition

Synonym
Bioavailability, uptake kinetics

Health condition

Nutritionele status (en dus preventief)

Research involving
Human

Sponsors and support

Primary sponsor: Vitux AS
Source(s) of monetary or material Support: Vitux AS, Oslo, Noorwegen,Vitux AS;Oslo;Noorwegen

Intervention

Keyword: bioavailability, fish oil, omega-3 fatty acids, supplements

Outcome measures

Primary outcome

The main study parameter is the sum of EPA and DHA plasma levels in venous blood samples collected at baseline (t=-15min and 0) and at t=30, 60, 90, 120, 150, 180, 240, 360, 540, and 720min (obtained from cannula) and 24hours (obtained via vena punction) after consumption of the different fish oil supplements.

Secondary outcome

NA

Study description

Background summary

Marine omega-3 triglyceride oils, rich in eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), are widely consumed as nutraceutical supplements due to their health benefits, such as improved cardiovascular health and reduced inflammation. The demand for these omega-3-rich oils as food supplements is increasing. However, studies indicate that the bioavailability of these oils may be higher in emulsified forms compared to bulk oils like those found in soft-gel capsules.

Study objective

To compare the plasma concentration versus time profiles and postprandial bioavailability of DHA and EPA after a nutritionally relevant oral dose of 1.1

gram (expressed as DHA + EPA) administered as either CCx gelatin-based soft chews (emulsified) or conventional gelatin-based soft gel capsules (bulk oil), both containing an identical omega-3 enriched fish oil, in healthy adults.

Study design

This intervention study has a randomized, cross-over, open label design

Intervention

Intervention: Study subjects will receive one of the 2 fish oil supplements in a randomized order

Study burden and risks

There are minor risks for the study subjects in this study. There are no direct benefits for the study subjects. In this research, we include healthy subjects based on the research criteria and a health questionnaire. The total amount of blood taken (170mL) is spread over two weeks, and individuals with anemia are excluded. Therefore, blood collection is not expected to pose any issues. Study subjects involved in the study will invest approximately 28.5 hours in the study. This study provides more insight into the effect of the formulation of fish oil supplements and in particular the effect of emulsified fish oil on the oral absorption of EPA and DHA. These findings can support the production and development of better alternatives for EPA and DHA supplementation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Apparently healthy adults (18 - 50 yrs);
- 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 2 weeks prior to the first postprandial test day;
- Willing to keep a stable dietary pattern throughout the study.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- 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, hypercholesterolemia, 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, 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 inhibitors, laxatives, and lipid lowering drugs, 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;

- Allergic for fish;
- Having swallowing problems with capsules;
- 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 to follow or having planned a slimming or medically prescribed diet;
- Use of recreational 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 substances 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 Wageningen Food & Biobased Research.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-11-2024
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	06-11-2024

Application type:	First submission
Review commission:	METC NedMec

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	NL87485.041.24
Other	Volgt nog (ClinicalTrials.gov)