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A study in healthy adults to compare the bioavailability of EPA + DHA from two microalgal sources to one fish source and placebo

Submission date
09/10/2025

Recruitment status
Recruiting

Registration date
13/10/2025

Overall study status
Ongoing

Last Edited
16/12/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Omega-3 fatty acids, particularly eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), are essential nutrients that our bodies need but cannot make efficiently on their own. These fatty acids are known to support heart health, reduce inflammation, and benefit overall wellbeing. People typically get omega-3s from eating oily fish or taking supplements.
There are two main sources of omega-3 supplements: fish oil and microalgal oil (made from algae). While both contain EPA and DHA, they come in slightly different forms and ratios. Fish oil is often processed into a form called re-esterified triglyceride (rTG), while microalgal oil naturally occurs as a natural triglyceride (nTG). Additionally, the balance of EPA to DHA differs between sources – microalgal oil typically has more DHA, while fish oil has more EPA.
The aim of this study is to compare how well the body absorbs and uses omega-3 fatty acids from two different microalgal oil products compared to a fish oil product. The researchers want to know if these plant-based alternatives work just as well as traditional fish oil supplements. This is important because it could provide sustainable, vegetarian-friendly alternatives to fish oil that are equally effective.

Who can participate?
This study is looking for 120 healthy adult volunteers, both men and women, aged between 18 and 64 years. Participants need to be generally healthy and not currently consuming much omega-3 in their diet (less than 200mg of EPA and DHA per day).
Women who are pregnant, breastfeeding, or planning to become pregnant cannot participate. Women of childbearing age must use effective contraception throughout the study.
Participants cannot take part if they have significant health conditions, allergies to fish or shellfish, bleeding disorders, or if they regularly take certain medications that might interfere with the study (such as blood thinners or high-dose anti-inflammatory drugs). People who regularly consume omega-3 supplements or eat fatty fish more than once per week, or who have smoked in the past 60 days, also cannot participate.

What does the study involve?
The study lasts 6 weeks and involves five clinic visits. Participants will be randomly assigned to one of four groups. Three groups will receive 900 mg daily of omega-3 (EPA and DHA combined) from either:
1. Microalgal oil with high DHA (life's Omega O1035DS)
2. Microalgal oil with balanced EPA and DHA (life's Omega O3020DS)
3. Fish oil (MEG-3)
The fourth group will receive a dummy treatment (placebo) containing corn and soybean oil with no omega-3.
Neither participants nor researchers will know which treatment each person receives until the study ends (this is called a double-blind study).
Participants will take three capsules daily with food for the entire 6 weeks. At the clinic visits, participants will:
1. Provide blood samples after fasting for 10 hours
2. Have vital signs measured (blood pressure, heart rate, temperature)
3. Have weight and other body measurements taken
4. Complete a questionnaire about their diet
The blood samples will be analyzed to measure how much EPA and DHA is in the blood and in red blood cell membranes (the Omega-3 Index). Researchers will also measure cholesterol and triglyceride levels, and may look at inflammatory markers and other health indicators.
Participants must maintain their usual diet and exercise habits throughout the study and avoid taking any other omega-3 supplements.

What are the possible benefits and risks of participating?
Benefits: Participants will receive free omega-3 supplements for 6 weeks (unless assigned to the placebo group). They will also receive comprehensive health screening, including blood tests for liver and kidney function, cholesterol levels, and other health markers. Participants will receive compensation of up to $500 for their time and travel expenses.
While there may not be direct health benefits from this short study, participants will be contributing to important research that could help others by identifying effective plant-based alternatives to fish oil supplements.
Risks: Omega-3 supplements are generally safe and well-tolerated. The most common side effects are mild digestive symptoms such as:
1. Stomach upset or nausea
2. Bloating or gas
3. Diarrhea
4. Fishy aftertaste or burps
These symptoms are usually mild and temporary. Participants who experience reflux can take the capsules separately with each meal rather than all at once.
Blood draws may cause temporary discomfort, bruising, or rarely, infection at the needle site. All blood samples will be collected by trained professionals following strict safety procedures.
The study products are manufactured to high quality standards and have been used safely in previous research. Participants will be closely monitored throughout the study, and any adverse events will be recorded and managed appropriately.

Where is the study run from?
The study is conducted at RDC Clinical in Fortitude Valley, Queensland, Australia. RDC Global Pty Ltd is the local sponsor in Australia.

When is the study starting and how long is it expected to run for?
June 2025 to December 2026

Who is funding the study?
dsm-firmenich Switzerland AG

Who is the main contact?
Dr David Briskey, research@rdcglobal.com.au

Contact information

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Scientific, Principal investigator

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Additional identifiers

ClinicalTrials.gov (NCT)
07241377

Study information

Scientific Title
A randomized, double-blind placebo-controlled study in healthy subjects to compare the bioavailability of EPA + DHA from two microalgal sources in natural triglyceride form to one fish source in re-esterified triglyceride form

Acronym

GOBO 2

Study objectives
The aim of this study is to compare the bioavailability of a natural triglyceride form of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) derived from microalgal oil at the same or different EPA to DHA ratio as the fish oil in a re-esterified triglyceride form. Two different microalgal oil formulations and one fish oil formulation will be compared with a placebo. It is assumed that fish and microalgal oil products will have higher plasma phospholipid values compared with placebo and similar to each other.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/09/2025, Bellberry Human Research Ethics Committee (123 Glen Osmond Road, Eastwood, South Australia, 5063, Australia; +61 (0)8 8361 3222; bellberry@bellberry.com.au), ref: 2025-07-1197

Study design
Single-site randomized double-blind placebo-controlled parallel assignment

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Absorption of omega-3

Interventions
Randomisation will be conducted by someone not involved in the conduct of the trial. The randomisation code for the IP will be generated by Random Allocation Software. The product will be randomised by a 1:1:1:1 ratio. Participants will be randomised to one of the four arms below and take the assigned study treatment for 6 weeks:

Arm 1: life'sTM Omega O1035DS nTG is a natural triglyceride (nTG) derived from microalgae with minimum 365 mg DHA, minimum 100 mg EPA, and minimum 520 mg/g DHA + EPA. All Omega-3 oils will be diluted with high oleic sunflower oil for a total (EPA + DHA) content of 300 mg /capsule. Each participant will consume three capsules for a total intake of 900 mg (EPA+DHA) /day for 6 weeks.

Arm 2: life'sTM Omega O3020DS nTG is a nTG derived from microalgae with minimum 210 mg DHA, minimum 300 mg EPA, and minimum 510 mg/g DHA + EPA. All Omega-3 oils will be diluted with high oleic sunflower oil for a total (EPA + DHA) content of 300 mg/capsule. Each participant will consume three capsules for a total intake of 900 mg (EPA+DHA)/day for 6 weeks.

Arm 3: MEG-3TM 3223 rTG (Comparator fish oil) is a re-esterified triglyceride (rTG) fish oil with minimum 230 mg DHA, minimum 320 mg EPA, and minimum 640 mg/g Omega-3. All Omega-3

oils will be diluted with high oleic sunflower oil for a total (EPA + DHA) content of 300 mg /capsule. Each participant will consume three capsules for a total intake of 900 mg (EPA+DHA) /day for 6 weeks.

Arm 4: The placebo capsules will be a mixture of corn and soybean oils. 515 mg corn oil and 515 mg soybean oil. Each participant will consume three capsules a day for 6 weeks.

Intervention Type
Supplement

Primary outcome(s)
Plasma phospholipids EPA+DHA µg/ml levels determined by gas chromatography (GC) from baseline to week 6

Key secondary outcome(s))
1. Plasma phospholipids EPA+DHA µg/ml levels determined by gas chromatography (GC) from baseline to weeks 2, 4, and 6
2. Omega-3 Index (percent of EPA + DHA in red blood cell membranes) determined by gas chromatography (GC) from baseline to week 6
3. Plasma phospholipids EPA+DHA µg/ml levels determined by gas chromatography (GC) from baseline to weeks 2 and 4
4. Total cholesterol, HDL- and LDL-cholesterol and triglyceride levels determined by a clinical analyser from baseline to week 6

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Written informed consent obtained before any trial related assessments are performed
2. Healthy adult females ages 18-64 years who are neither pregnant nor breastfeeding or healthy adult males aged 18-64 years at the time of consent
Female participants of child-bearing potential (females who are postmenopausal, i.e., when there has been no menstruation for a minimum of 12 months prior to screening, are considered not to be of childbearing potential), who are not surgically sterilized, must have a negative pregnancy test at screening and be willing to practice one of the following appropriate contraceptive methods until the last visit:
2.1. Sexual abstinence
2.2. Oral contraceptives
2.3. Transdermal patches or depot injection of a progestogen drug (starting at least 4 weeks prior to product administration)
2.4. Intrauterine device (IUD), intrauterine system (IUS), subdermal implant, or vaginal ring (placed at least 4 weeks prior to product administration)
2.5. Contraceptives must be effective before the randomization visit
3. Participant’s body mass index (BMI) must be between 18 and 30 kg/m2 (inclusive) and participant must weigh a minimum of 50 kg (110 lbs)
4. Intakes of EPA+DHA of <200 mg per day based on the FFQ
5. Agree not to change current diet and exercise frequency or intensity during entire study period

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
64 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Participant has any health conditions that would prevent from fulfilling the study requirements, put the participant at risk or would confound the interpretation of the study results as judged by the Investigator based on medical history and routine laboratory test results.
2. History or presence of clinically significant cardiovascular, pulmonary, hepatic, renal, haematologic, gastrointestinal, endocrine, immunologic, dermatologic, neurologic, oncologic, or psychiatric disease or any other condition that, in the opinion of the Investigator, would jeopardize the safety of the subject or the validity of the study results.
3. Has a clinically significant abnormal finding on the medical assessment, medical history, vital signs or clinical laboratory results at screening.
4. History or presence of allergic or adverse response to omega-3-acid ethyl esters or triglycerides (EPA or DHA), or related drugs, or sensitivity or allergy to fish or shellfish, or soybean or corn.
5. History of coagulation disorder or current anticoagulation therapy.
6. Has been on a significantly abnormal* diet, as deemed by the investigator, during the 4 weeks preceding the first dose of study medication. *an abnormal diet will be considered if the participant has elected to change to a more or less restricted diet of any description (e.g., change to or from a vegetarian, vegan, gluten-free, lactose-free, etc.) or significantly increases or decreases their daily caloric intake.
7. Has participated in another clinical trial (randomised participants only) within 30 days prior to the first dose of study medication.
8. Has used prescription medication (excluding oral contraceptive and hormonal replacement therapy) within 4 weeks of screening or OTC medication within 7 days before the first dose that may affect omega-3 absorption or any study outcomes. This may include but is not limited to: high-dose NSAIDs, bile acid sequestrants, statins, GLP-1 receptor agonists, anticoagulants and anti-inflammatory drugs. Occasional ibuprofen, paracetamol and low-dose aspirin use is permitted.
9. Regular use* of omega-3 supplements and/or regular fatty fish consumption within 2 months. *Regular use is defined as more than once per week of either fish oil, krill oil, microalgal oil

supplements, or fatty fish.
10. Has smoked or used tobacco products within 60 days prior to the first dose of study medication.
11. History of substance abuse or treatment (including more than 14 alcoholic drinks per week) within the past 2 years based on the judgement of the investigator.
12. Has a positive urine screen for drugs of abuse (amphetamines, barbiturates, benzodiazepines, cocaine, cannabinoids, opiates).
13. Has increased bleeding from existing pathological conditions or anticipates surgery (including dental) prior to, throughout, or within 1 week after study participation.
14. Has had a transient ischemic attack (TIA) or stroke or is at high risk for recurrent ischemic events

Date of first enrolment
27/10/2025

Date of final enrolment
15/04/2026

Locations

Countries of recruitment
Australia

Study participating centre
RDC Clinical
Level 3, 252 Saint Pauls Terrace
Fortitude Valley
Australia
4006

Sponsor information

Organisation
dsm-firmenich Switzerland AG

Organisation
RDC Global

Funder(s)

Funder type

Industry

Funder Name
dsm-firmenich Switzerland AG

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from will be made available upon reasonable request to the PI (Dr David Briskey, research@rdcglobal.com.au) or Sponsor.

IPD sharing plan summary
Available on request