A Study in Healthy Adults to Compare the Bioavailability of EPA + DHA From Two Microalgal Sources to One Fish Source and Placebo

NCT07241377

Status	RECRUITING
Phase	Phase 3
Sponsor	RDC Clinical Pty Ltd
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (8)

- Written informed consent obtained before any trial related assessments are performed.
- Healthy adult females ages 18-64 who are neither pregnant nor breastfeeding or healthy adult males ages 18-64 at the time of consent.
- a. Female participants of child-bearing potential (females who are post-menopausal, i.e., when there has been no menstruation for a minimum of 12 months prior to screening, are considered not to be of child-bearing 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: i. Sexual abstinence. ii. Oral contraceptives. iii. Trans dermal patches or depot injection of a progestogen drug (starting at least 4 weeks prior to product administration).
- iv. Intrauterine device (IUD), intrauterine system (IUS), subdermal implant, or vaginal ring (placed at least 4 weeks prior to product administration).
- v. Contraceptives must be effective before the randomization visit.

... and 3 more (see full listing online)

Exclusion (14)

- 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.
- 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.
- Has a clinically significant abnormal finding on the medical assessment, medical history, vital signs or clinical laboratory results at screening.
- 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.
- History of coagulation disorder or current anticoagulation therapy.

... and 9 more (see full listing online)

Locations (1 total)

RDC Clinical, Fortitude Valley, Queensland, Australia