

Trial record **4 of 6** for: samuel fortin

◀ Previous Study


|

Return to List

|


Next Study ▶


Comparative Study of Three Different Formulations of Omega-3 (EPA+DHA)




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ClinicalTrials.gov Identifier: NCT04159532

Recruitment Status  : Completed

First Posted  : November 12, 2019

Last Update Posted  : April 29, 2021

[View this study on Beta.ClinicalTrials.gov](#)

Sponsor:  
SCF Pharma

Information provided by (Responsible Party):  
SCF Pharma

Study Details

Tabular View

No Results Posted




Disclaimer

 How to Read a Study Record

Study Description

Go to ▾


**Brief Summary:**  
This pilot study aims at comparing the bioavailability of three different formulations of the omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The three formulations are ethyl ester (EE), triglyceride (TG) and monoglyceride (MAG). Thirty six (36) subjects will be divided in three groups of twelve subjects each equally divided in two study sites. Each group will be taking one of the three different formulations of EPA+DHA at a daily dose of 1.5g for a period of 12 weeks. Bioavailability will be measured through omega-3 index (total content of EPA + DHA in red blood cell membranes) at baseline and every four weeks during treatment.


Condition or disease 	Intervention/treatment 	Phase 
Healthy Adults	Dietary Supplement: MAG-EPA/MAG-DHA Dietary Supplement: TG-EPA/TG-DHA Dietary Supplement: EE-EPA/EE-DHA	Phase 4

**Detailed Description:**  
This pilot study aims at comparing the bioavailability of three different formulations of a combination of omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in a standardized proportion of 460:200. The three formulations are ethyl ester (EE), triglyceride (TG) and monoglyceride (MAG) versions of these fatty acids. The formulations are prepared in a way to be similar in proportion of EPA/DHA, in dose and in appearance. Thirty six (36) subjects will be divided in three groups of twelve subjects each, equally divided in two study sites. The study will be randomized and double blinded. Each group will be taking one of the three different formulations of EPA+DHA at a daily dose of 1.5g for a period of 12 weeks. Bioavailability will be measured through omega-3 Index (total content of EPA + DHA in red blood cell membranes) at baseline and every four weeks during treatment. After recruitment, subjects will be seen in clinic every four weeks for a total of four (4) study visits during which a blood sample will be taken for analysis of the omega-3 Index, the investigational product will be returned and dispensed and finally, adverse events will be noted and followed. Treatment will be self-administered by subjects at home. They will be asked to keep a journal of adverse events, concomitant medication and to note every missed dose as well as significant changes in life habits (smoking, alcohol, sports, food diet and natural health products intake).

Study Design

Go to ▾

Study Type  : Interventional (Clinical Trial)

Actual Enrollment  : 36 participants

Allocation: Randomized

Intervention Model: Parallel Assignment


Intervention Model Description: Double-blind, 3-arms parallel randomized study.


Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)


Masking Description: Double blinded. Only the sponsor will have access to the randomisation list. No one at the sites will have access to the list.

Primary Purpose: Basic Science

Official Title: Comparative Bioavailability Study of Monoglyceride (MAG) Versus Triglyceride (TG) Versus Ethyl Ester (EE) Formulations of Eicosapentaenoic (EPA) and Docosahexaenoic (DHA) Acids. Pilot Study (IC3-03)



Actual Study Start Date  : December 18, 2019

Actual Primary Completion Date  : February 25, 2021

Actual Study Completion Date  : February 25, 2021

Arms and Interventions

Go to ▾

Arm 	Intervention/treatment 
Experimental: Monoglyceride (MAG) Group A will receive the omega-3 fatty acids in monoglyceride formulation (MAG). Subjects will receive 1.5g per day of MAG-EPA/MAG-DHA in a proportion of 460:200 for 12 consecutive weeks.	Dietary Supplement: MAG-EPA/MAG-DHA monoglyceride of eicosapentaenoic acid and docosahexaenoic acid in proportion of 460:200
Active Comparator: Triglyceride (TG) Group B will receive the omega-3 fatty acids in triglyceride formulation (TG). Subjects will receive 1.5g per day of TG-EPA/TG-DHA in a proportion of 460:200 for 12 consecutive weeks.	Dietary Supplement: TG-EPA/TG-DHA Triglyceride of eicosapentaenoic acid and docosahexaenoic acid in proportion of 460:200
Active Comparator: Ethyl Ester(EE) Group C will receive the omega-3 fatty acids in Ethyl ester formulation (EE). Subjects will receive 1.5g per day of EE-EPA/EE-DHA in a proportion of 460:200 for 12 consecutive weeks.	Dietary Supplement: EE-EPA/EE-DHA Ethyl ester of eicosapentaenoic acid and docosahexaenoic acid in proportion of 460:200