

Double-blind, placebo-controlled, randomised, clinical trial of eicosapentaenoic acid in the treatment of mood disorders among middle-aged women

Submission date 20/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/01/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Study objectives

To determine whether fish oil supplement rich in eicosapentaenoic acid (EPA) is more effective than placebo (sunflower oil) in reducing distress and depressive symptoms over eight weeks.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This project received ethics approval on March 25, 2004 from the Ethical Committee of the clinical research of the Saint-François d'Assise Hospital. On the 17th December 2004 we received, for this study, the agreement of the Bureau Product Review and Assessment (BPRA) of the Natural Health Products Directorate (NHPD) of Health (Canada).

Study design

Double-blind, placebo-controlled, randomised, clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mild to moderate major depression, moderate to severe psychological distress

Interventions

Women will be randomly assigned to a dietary supplement (OM3®) rich in omega-3 fatty acids (1.2 g/day) or a placebo (sunflower oil) for a period of eight weeks. Each capsule will be provided by Isodis Natura. Each 500 mg capsule of OM3® contains 350 mg of EPA and 50 mg of Docosahexaenoic Acid (DHA). Women will have to take one capsule three times a day (before each meal). The three omega-3 capsules will correspond to a daily intake of 1.05 g of EPA and 150 mg of DHA for a total of 1.2 g of omega-3 fatty acids per day.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA)

Primary outcome(s)

Psychological distress based on General Well-Being Scale (GWB) administered at baseline, four and eight weeks.

Key secondary outcome(s)

1. Hamilton-21 Depression (HAM-D) Rating Scale administered at baseline and eight weeks
2. Depression subscale of the Symptom Check-List-90-R (SCL-Dep) administered at baseline, four and eight weeks
3. Frequency and severity of menopause vasomotor symptoms administered at baseline, four and eight weeks
4. Quality of life (MENopause Specific Quality Of Life [MENQOL], Short Form health survey [SF36], fatigue, sexual activities, work limitations, sleep problems) administered at baseline and eight weeks
5. Clinical Global Impression of improvement evaluated by doctor (CGI) and by the patient (Patient Global Impression of Improvement [PGI-I]) administered at baseline and eight weeks

Completion date

01/02/2007

Eligibility**Key inclusion criteria**

1. Women between 40 and 55 years of age
2. Moderate to severe psychological distress based on General Well-Being Scale (GWB) (score less than 72)
3. Have a negative results on a pregnancy test and currently using an adequate method of contraception
4. Provision of signed informed consent for participation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Hamilton-21 score of 26 or more, or Patient Health Questionnaire (PHQ-9) score of 20 or more
2. Past or current history of schizophrenia or bipolar I disorders
3. Current or significant imminent risk of suicide or homicide
4. Post-menopausal for more than five years
5. Major medical disorders such as malabsorption disease, gastrectomy and acute pancreatitis
6. Inherited or acquired disease of the haemostatic or the coagulation
7. Medical conditions that interfere with the digestion and the absorption of medication
8. Taking antihypertensive medications or suffer from hypercholesterolaemia or diabetes type two
9. Endocrine diseases that could be linked to psychiatry
10. Others medical causes that could be linked to psychiatry
11. Have a current substance abuse disorders such as drugs (marijuana, cocaine, etc.) or alcohol

(more than 40 g of alcohol by day)

12. Fish allergies

13. Have regularly consumed fish (more than three serving per week) in the last months

14. Have taken antidepressant medication or hormone replacement therapy (HRT) or St-Johns Wort (*Hypericum Perforatum*) in the last six months before enrolment

15. Current use of any drugs that thin blood such as aspirin, ibuprofen, heparin, clopidogel, warfarin, dalteparin, dipyrimadole, enoxaparin, ticlopidine, ginkgo or other anticoagulants

Date of first enrolment

01/03/2005

Date of final enrolment

01/02/2007

Locations

Countries of recruitment

Canada

Study participating centre

Foundation Lucie et André Chagnon

Québec

Canada

G1L 2G1

Sponsor information

Organisation

Foundation Lucie et André Chagnon (Canada)

ROR

<https://ror.org/05ret9323>

Funder(s)

Funder type

Charity

Funder Name

Foundation Lucie et André Chagnon, Laval University (Canada)

Funder Name

Isodis Natura (Canada)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2009		Yes	No