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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

Registration date
13/02/2007

Overall study status
Completed

Last Edited
06/01/2009

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 Docosahexaeonic 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), docosahexaeonic acid (DHA)

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

Secondary outcome measures
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

Overall study start date
01/03/2005

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

Age group
Adult

Sex
Female

Target number of participants
144

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
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Sponsor information

Organisation
Foundation Lucie et André Chagnon (Canada)

Sponsor details
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Sponsor type
Charity

Website
http://www.fondationchagnon.org

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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