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Treating Depression with Omega-3

Submission date 09/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 31/10/2005	**Overall study status** Completed	
Last Edited 02/11/2011	**Condition category** Mental and Behavioural Disorders	

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
Double-blind, placebo-controlled, randomised trial of eicosapentaenoic acid (EPA) for major depression

Acronym
Omega-3-D

Study objectives
1. To determine whether 1050 mg per day of eicosapentaenoic acid (EPA) is more effective than placebo (sunflower oil) in reducing depressive symptoms over 8 weeks
2. To report data on the tolerability and the safety of EPA in comparison to placebo

Please note that as of 14/01/2009 this record was updated to include the actual start and end dates of the trial. The initial anticipated trial dates were as follows:
Initial anticipated start date: 21/09/2005
Initial anticipated end date: 21/09/2007

Please also note that the target sample size at the end of recruitment was 432 participants; the initial target number of participants was 508. This target sample size change was approved by the Data and Safety Monitoring Committee in June 2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Centre Hospitalier de lUniversité de Montréal Research Ethics Board gave approval on the 30th March 2005 (ref: SL-05.036)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information material can be found on http://www.omega3d.com/3_etude/en_etude_01.html

Health condition(s) or problem(s) studied

Major depression

Interventions
Participants are randomly assigned to take three capsules per day of 500 mg of omega-3 fish oil supplement or a matched sunflower oil placebo (low in omega-3 and omega-6) for 8 weeks. The fish oil supplement consist of the OM3 formula marketed by Isodis Natura containing 70% EPA-5% DHA fish oil ethyl-ester, which provides the equivalent of 1050 mg of eicosapentaenoic acid (EPA) and 150 mg of docosahexaenoic acid (DHA) per day.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Eicosapentaenoic acid (EPA)

Primary outcome measure
The 30-item Inventory of Depressive Symptomatology, self-report (IDS-SR), administered at baseline, 1, 2, 4 and 8 weeks.

Secondary outcome measures
1. The Montgomery-Asberg Depression Rating Scale (MADRS) will be completed at baseline, 1, 2, 4 and 8 weeks to allow comparison with standard pharmaceutical trials
2. Rate, type and severity of non-serious adverse events
3. Rate and type of serious adverse events

Overall study start date
17/10/2005

Completion date
05/12/2008

Eligibility

Key inclusion criteria
1. Greater than 18 years of age, either sex
2. Current diagnosis of major depressive episode based on the Mini-International Neuropsychiatric Interview (MINI version 5.0.0)
3. Inventory of Depressive Symptomatology (IDS-SR) score greater or equal to 27
4. Presence of significant depressive symptoms for at least 4 weeks, as judged by the clinician
5. If on antidepressants, has been at maximum recommended tolerable dosage for greater than 4 weeks
6. If not on antidepressants, has been either intolerant to at least two previous trials of antidepressants or refuses to take an antidepressant despite medical advice
7. Provision of signed informed consent for participation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
432

Key exclusion criteria
1. Known allergy to fish or sunflower oil
2. Known intolerance of fish oil supplements
3. Has taken greater than 28 capsules of fish oil supplements during the last 4 weeks
4. Current alcohol or drug abuse or dependency based on the MINI
5. Bipolar disorder based on the MINI
6. Significant suicidal risk based on clinical judgement
7. Pregnant women (all non-menopausal women will need to have a negative pregnancy test before randomisation) and those planning to become pregnant over the course of the trial, or women of child bearing potential not using an accepted method of contraception
8. With coagulation diseases and/or subjects regularly taking any drugs or herbs that thin the blood such as aspirin, heparin, clopidogrel, warfarin, dalteparin, dipyrdamole, enoxaparin, ticlopedine, and gingko
9. History of myocardial infarction
10. Pancreatic insufficiency
11. Investigator's judgement that the patient is unable/unwilling to comply with study regimen

Date of first enrolment
17/10/2005

Date of final enrolment
05/12/2008

Locations

Countries of recruitment
Canada

Study participating centre
Department of Psychiatry
Montreal
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Sponsor information

Organisation
University Hospital of Montreal (CHUM) Research Centre (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.chumontreal.qc.ca

ROR
https://ror.org/0410a8y51

Funder(s)

Funder type
Industry

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	01/08/2011	Yes	No