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Omega 3 fatty acid treatment in patients with epilepsy

Submission date
13/05/2014

Recruitment status
No longer recruiting

Registration date
20/08/2014

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Eating foods rich in omega 3 fatty acids, EPA and DHA is considered to be very good for us. There is a lot of evidence to suggest they help prevent a number of diseases, including cardiovascular (for example heart) disease and neurological (for example brain) disease as well as maintain the normal functioning of both the heart and the brain. It is also thought that they may help in reducing drug-induced toxicity and boosting how well a drug works against a disease. It is possible that omega 3 fatty acids will help patients with epilepsy by reducing the number of seizures that they have and by making those that they do have, less severe. It is also thought that they may prevent the cardiac arrhythmia (irregular beating of the heart) and sudden unexpected death that can happen after a seizure and help control the psychological effects of the disease. As there is evidence that seizures may result in inflammation, epileptic patients may also benefit from the anti-inflammatory effects of omega 3 fatty acids. Here, we will investigate how omega 3 fatty acids may help to prevent patients with difficult to treat epilepsy for which there is no known cause (refractory idiopathic epilepsy) from having seizures and reduce the possibility of dying from them.

Who can participate?
Patients with refractory idiopathic epilepsy, aged 17 to 50 years.

What does the study involve?
Patients are randomly allocated into one of two groups. Those in group 1 are asked to take an omega 3 supplement contains 1.5g DHA and 390mg EPA for one year. Those in group 2 take a placebo (dummy pill). Blood samples are collected from all participants at the start and end of the trial for analysis. Clinical history, neurological and psychological/psychiatric assessments are also carried out at the start and end of the trial.

What are the possible benefits and risks of participating?
Each participant will receive a close monitoring throughout the study duration. There is no risk to participating.

Where is the study run from?
The study has been set up by the Lipidomics and Nutrition Research Centre, Faculty of Life

Sciences and Computing, London Metropolitan University (UK) in collaboration with the University of Khartoum Hospital, Khartoum (Sudan).

When is study starting and how long is it expected to run for?
September 2014 to February 2017

Who is funding the study?
Lipidomics and Nutrition Research Centre, London (UK)
University of Khartoum Hospital (Sudan)
Efamol Limited (UK)

Who is the main contact?
Professor Kebreab Ghebremeskel,
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Contact information

Type(s)
Scientific

Contact name
Prof Kebreab Ghebremeskel

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Additional identifiers

Protocol serial number
EPILOEMGA3 v1

Study information

Scientific Title
Omega 3 fatty acid supplementation to prevent seizure in patients with refractory epilepsy

Acronym
EPILOMEGA3

Study objectives
1. Core null hypothesis: Patients with refractory epilepsy do not have abnormal plasma and blood cell fatty acids; Supplementation with the long-chain polyunsaturated omega 3 fatty acids,

EPA and DHA, will not prevent seizures in patients with refractory epilepsy.
2. Subsidiary null hypothesis: Refractory epileptics supplemented with EPA and DHA will not have enhanced mental performance, cognition and memory.
3. Nested null hypotheses: Treatment of refractory epileptic patients with EPA and DHA will not improve behavioural and psychiatric disorders; modulate clinical markers of cardiac arrhythmias; down-regulate inflammatory markers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Faculty of Medicine, University of Khartoum, Sudan, 26/11 /2012

Study design
Double-blind placebo-controlled randomised intervention trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Epilepsy

Interventions
1. Active supplement (contains 1.5g DHA and 390mg EPA)
2. Placebo (1.9g of saturated and monounsaturated fatty acid blend)

Intervention Type
Supplement

Primary outcome(s)
Complete elimination or reduction in the frequency seizures

Key secondary outcome(s)
1. Improvements of cognition, memory, and manifestations of behavioural and psychiatric disorders 2. Modulation of clinical markers of cardiac arrhythmias; down regulation of inflammatory markers

Completion date
28/02/2017

Eligibility

Key inclusion criteria
Patients with refractory idiopathic epilepsy, aged 17 to 50 years

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
99

Key exclusion criteria
1. Age under 17 and over 50 years
2. Other diseases in addition to epilepsy
3. Structural lesions
4. Pregnancy
5. Responsive to AED
6. Less than two seizures a month

Date of first enrolment
01/09/2014

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
United Kingdom

England

Sudan

Study participating centre
London Metropolitan University
London
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N7 8DB

Sponsor information

Organisation
Faculty of Life Sciences and Computing, London Metropolitan University (UK)

ROR
https://ror.org/00ae33288

Funder(s)

Funder type
University/education

Funder Name
Lipidomics and Nutrition Research Centre, London Metropolitan University, London (UK)

Funder Name
University of Khartoum Hospital (Sudan)

Funder Name
Efamol Limited (UK)

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		01/10/2018	10/05/2021	Yes	No