

Double-blind parallel study of Omega-3 fatty acid supplement in patients with refractory epilepsy

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/08/2013	Condition category Nervous System Diseases	<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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0263120045

Study information

Scientific Title

Study objectives

To assess the effect of Omega-3 supplementation on seizure frequency in patients with refractory epilepsy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Double blind parallel randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Nervous System Diseases: Epilepsy

Interventions

1. Omega-3 fatty acid
2. Olive oil

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Omega-3 fatty acid and olive oil

Primary outcome measure

Seizure frequency and adverse events

Secondary outcome measures

1. Antiepileptic drug (AED) levels
2. Patients' global impression
3. Behaviour and mood probes
4. Hamilton Depression rating scale
- 5 Plasma and red blood cell (RBC) fatty acid concentrations
6. Magnetic resonance (MR) spectroscopic measurement of phosphomonoester and phosphodiester
6. Changes in total brain volume

Overall study start date

01/02/2003

Completion date

01/08/2005

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

52 patients from Epilepsy Department

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/02/2003

Date of final enrolment

01/08/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Clinical Neurology
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Charity

Funder Name
University College London Hospitals NHS Trust (UK)

Funder Name
National Society for Epilepsy (UK)

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	01/09/2005		Yes	No