

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

☐ Prospectively registered

☐ Protocol

Registration date
12/09/2003

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
28/08/2013

Condition category
Nervous System Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr M Koepp

Contact details

Clinical Neurology
National Hospital for Neurology/Neurosurgery
Queen Square
London
United Kingdom
WC1N 3BG
+44 (0)20 7837 3611

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Double blind parallel randomised controlled trial

Study type(s)

Treatment

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(s)

Seizure frequency and adverse events

Key secondary outcome(s)

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

Completion date

01/08/2005

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Clinical Neurology

London

United Kingdom

WC1N 3BG

Sponsor information

Organisation

Department of Health (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

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