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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 28/08/2013	**Condition category** Nervous System Diseases	

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

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