A multicentre, multinational, double blind, randomised, parallel group, placebo-controlled study of ethyl-eicosapentaenoate (EPA) in patients with Huntington's disease (HD)

Submission date 03/02/2003	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 03/02/2003	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 09/02/2011	Condition category Nervous System Diseases	Individual participant da

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

- d
- ata

ClinicalTrials.gov number

Secondary identifying numbers LA01.01.0005

Study information

Scientific Title

Study objectives Not provided at time of registration

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Not Specified

Participant information sheet

Health condition(s) or problem(s) studied Huntington's disease

Interventions Two groups randomly allocated to placebo or 2 g/day ethyl EPA on a double blind basis.

Patients who completed the 12 month randomisation phase of the trial were invited to take part in a further 12 month open label phase receiving 2 g/day Ethyl EPA.

Intervention Type Other

Phase Not Specified **Primary outcome measure** Not provided at time of registration

Secondary outcome measures Not provided at time of registration

Overall study start date 01/01/2003

Completion date 01/01/2004

Eligibility

Key inclusion criteria

 Written informed consent
 Availability of a responsible family member or carer to look after the patient during the trial and ensure complete compliance
 Diagnosis of HD in stage I

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants Not provided at time of registration

Key exclusion criteria Not provided at time of registration

Date of first enrolment 01/01/2003

Date of final enrolment 01/01/2004

Locations

Countries of recruitment Scotland

United Kingdom

Study participating centre Laxdale Ltd Stirling United Kingdom FK7 9JQ

Sponsor information

Organisation Laxdale Ltd (UK)

Sponsor details

Kings Park House Laurelhill Business Park Polmaise Road Stirling United Kingdom FK7 9JQ +44 (0)1786 476001 admin@Laxdale.co.uk

Sponsor type Industry

Website http://www.laxdale.co.uk

ROR https://ror.org/03gc62f43

Funder(s)

Funder type Industry

Funder Name Laxdale Ltd (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?
<u>Results article</u>	results	26/07/2005		Yes	No