

A multicentre, double-blind, randomised, parallel group, placebo-controlled, dose-ranging pilot study of ethyl-eicosapentaenoate (ethyl-EPA) in patients with schizophrenia

Submission date 01/07/2001	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/07/2001	Overall study status Completed	☐ Protocol
Last Edited 07/09/2007	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

LA.01.01.0001

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

Four groups were randomly allocated to placebo or 1 g, 2 g or 4 g ethyl-EPA/day on a double blind basis. Treatment duration 12 weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ethyl-eicosapentaenoate (ethyl-EPA)

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/06/2001

Eligibility

Key inclusion criteria

1. Written informed consent
2. Diagnosis of schizophrenia according to Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria
3. Minimum duration of 12 weeks from diagnosis
4. Maximum duration of 20 years from diagnosis
5. Maintained on same neuroleptic drug(s) for 12 weeks and on the same dose for 4 weeks
6. Total Positive and Negative Syndrome Scale (PANSS) score of 50 or more and a positive sub-scale PANSS score of 15 or more
7. Aged 18 - 65 of either sex
8. In-patient or out-patient

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/06/2000

Date of final enrolment

01/06/2001

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre

Laxdale Ltd

Stirling

United Kingdom

FK7 9JQ

Sponsor information

Organisation

Laxdale Ltd (UK)

ROR

<https://ror.org/03gc62f43>

Funder(s)

Funder type

Industry

Funder Name

Laxdale Ltd (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	01/01/2002		Yes	No