ISRCTN44218911 https://doi.org/10.1186/ISRCTN44218911

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

Registration date
01/07/2001

Last Edited
07/09/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

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
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
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United Kingdom
FK7 9JQ

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?
Results article	Results	01/01/2002		Yes	No