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A multicentre, double-blind, randomised, parallel group, placebo-controlled trial of LAX-101 (ethyl eicosapentaenoate [EPA]) as adjunct therapy in patients who remain depressed following treatment with standard antidepressant therapy

Submission date
03/02/2003

Registration date
03/02/2003

Last Edited
18/10/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
LA01.01.0006

Study information

Scientific Title
A multicentre, double-blind, randomised, parallel group, placebo-controlled trial of LAX-101 (ethyl eicosapentaenoate [EPA]) as adjunct therapy in patients who remain depressed following treatment with standard antidepressant therapy

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression

Interventions
Two groups randomly allocated to:
1. Placebo
2. 1 g/day ethyl EPA
on a double-blind basis.

Patients who completed the 12-week randomisation phase of the trial were invited to take part in a further 12-month open-label phase receiving 1 g/day ethyl EPA.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ethyl eicosapentaenoate

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/01/2004

Eligibility

Key inclusion criteria
1. Written informed consent
2. Score of greater than or equal to 16 on the Hamilton Depression Rating Scale (HDRS)
3.Treatment for greater than or equal to 8 weeks with one or more standard antidepressant, at stable dose for greater than or equal to 3 weeks
4. Currently receiving at least the minimum therapeutic dose of one or more standard antidepressant, as defined in the British National Formulary (BNF)
5. Diagnosis of major depressive disorder (Diagnostic and Statistical Manual of Mental Disorders, Fourth edition [DSM-IV])
6. Male or female of any race aged 18-75

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

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
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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes