

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/02/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/10/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 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

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 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

01/01/2003

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

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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