ISRCTN63565713 https://doi.org/10.1186/ISRCTN63565713

A multicentre, double-blind, randomised, parallel group, placebo-controlled trial of LAX-101 (ethyl eicosapentaenoate [EPA]) in patients with a new or recurrent episode of depression

Submission date
03/02/2003

Recruitment status
No longer recruiting

Registration date
03/02/2003

Overall study status
Completed

Last Edited
11/10/2016

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
LA01.01.0008A

Study information

Scientific Title
A multicentre, double-blind, randomised, parallel group, placebo-controlled trial of LAX-101 (ethyl eicosapentaenoate [EPA]) in patients with a new or recurrent episode of depression

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
Four groups randomly allocated to placebo, 0.5 g, 1 g or 2 g/day ethyl EPA on a double-blind basis.

Intervention Type
Other

Phase
Not Specified

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. Diagnosis of major depressive disorder (Diagnostic and Statistical Manual of Mental Disorders, Fourth edition [DSM-IV])
3. Score of between and including 16 and 25 on the Hamilton Depression Rating Scale (HDRS)
4. No treatment with any antidepressant medication (including St John's Wort) in the last 12 weeks from the date of Visit 0 (screen)
5. 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