

# 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

|                                        |                                                               |                                                      |
|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>03/02/2003   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>03/02/2003 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>11/10/2016       | <b>Condition category</b><br>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

### 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