

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

LA01.01.0008A

## **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

### **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**

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 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. 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

**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

Kings Park House

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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