

A multicentre, double-blind, randomised, parallel group, placebo-controlled, dose ranging pilot study of ethyl eicosapentaenoate (EPA) as adjunct therapy in patients who remain depressed following treatment with standard antidepressant therapy

Submission date 26/02/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/02/2002	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

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Additional identifiers

Protocol serial number

LA01.01.0002

Study information

Scientific Title

A multicentre, double-blind, randomised, parallel group, placebo-controlled, dose ranging pilot study of 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

Multicentre double-blind randomised parallel-group placebo-controlled dose-ranging pilot study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Depression

Interventions

Four groups randomly allocated to placebo or 1 g, 2 g or 4 g ethyl-EPA/day on a double-blind basis. Treatment duration: 12 weeks.

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

31/12/2002

Eligibility

Key inclusion criteria

1. Written informed consent
2. Hamilton score of 14 or more
3. Treatment for =8 weeks with one or more standard antidepressants, with no change in antidepressant dosage or drug for at least 4 weeks; likely to be maintained on this treatment and dosage for the duration of the study
4. Diagnosis of major depressive disorder (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition [DSM IV])
5. Male or female, of any race, aged 18-65

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2002

Date of final enrolment

31/12/2002

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