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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

Registration date
26/02/2002

Last Edited
18/10/2016

Recruitment status
No longer recruiting

Overall study status
Completed

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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 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
01/01/2002

Date of final enrolment
31/12/2002

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