ISRCTN44218911 https://doi.org/10.1186/ISRCTN44218911

# A multicentre, double-blind, randomised, parallel group, placebo-controlled, dose-ranging pilot study of ethyl-eicosapentaenoate (ethyl-EPA) in patients with schizophrenia

**Submission date**
01/07/2001

**Registration date**
01/07/2001

**Last Edited**
07/09/2007

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Harald Murck

**Contact details**
Laxdale Ltd
Kings Park House
Laurelhill Business Park
Polmaise Road
Stirling
United Kingdom
FK7 9JQ
+44 (0)1786 476001
hmurck@laxdale.co.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
LA.01.01.0001

# Study information

**Scientific Title**

**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)**
Hospital

**Study type(s)**
Treatment

**Participant information sheet**

**Health condition(s) or problem(s) studied**
Schizophrenia

**Interventions**
Four groups were 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 Specified

**Drug/device/biological/vaccine name(s)**

Ethyl-eicosapentaenoate (ethyl-EPA)

### Primary outcome measure
Not provided at time of registration

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/06/2000

### Completion date
01/06/2001

## Eligibility

### Key inclusion criteria
1. Written informed consent
2. Diagnosis of schizophrenia according to Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria
3. Minimum duration of 12 weeks from diagnosis
4. Maximum duration of 20 years from diagnosis
5. Maintained on same neuroleptic drug(s) for 12 weeks and on the same dose for 4 weeks
6. Total Positive and Negative Syndrome Scale (PANSS) score of 50 or more and a positive sub-scale PANSS score of 15 or more
7. Aged 18 - 65 of either sex
8. In-patient or out-patient

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 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
01/06/2000

### Date of final enrolment

01/06/2001

# 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
Laurelhill Business Park
Polmaise Road
Stirling
United Kingdom
FK7 9JQ

### 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | Results | 01/01/2002 | | Yes | No |