ISRCTN90916365 https://doi.org/10.1186/ISRCTN90916365

Lamotrigine And Borderline personality disorder: Investigating Long term Effectiveness

Submission date
12/06/2012

Recruitment status
No longer recruiting

Registration date
01/08/2012

Overall study status
Completed

Last Edited
11/07/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People with borderline personality disorder have poor mental health and may experience sudden and distressing changes in mood. No medication is currently licensed to help people with borderline personality disorder and treatment options for patients are therefore limited. Lamotrigine is a mood stabiliser which has been successfully used to help people with mood disorders. The aim of this study is to test whether adding lamotrigine to usual treatment for people with borderline personality disorder improves mental health and is a cost-effective use of resources.

Who can participate?
People aged 18 or over who are in contact with mental health services in England and have a diagnosis of borderline personality disorder.

What does the study involve?
All those who take part in the study receive a full assessment of their mental health, social functioning and use of healthcare services before their entry into the study. All those who take part in the study have three follow-up assessments, 12, 24 and 52 weeks after their entry into the study. Half the study participants are prescribed lamotrigine and the other half are prescribed a placebo (dummy) which is identical in appearance to the lamotigine but does not contain any active drug. All people in the study continue to have access to services including other drug treatments.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part, but study participants will be helping make sure that in the future people with borderline personality disorder receive better treatment. There are no risks from taking the part other than people who receive lamotrigine may experience side effects from taking this medication.

Where is the study run from?
The study is run from the Centre for Mental Health at Imperial College London in collaboration

with University of Nottingham, Tees, Esk & Wear Valleys NHS Foundation Trust, Kings College London, Central and North West London NHS Foundation Trust, Oxleas NHS Foundation Trust, and Nottinghamshire Healthcare NHS Trust

When is the study starting and how long is it expected to run for?
We will start to recruit study participants in early 2013. Recruitment is due to end in 2015 and the results of the study are due to be published at the end of 2017. Each study participant will be followed-up for at least one year, but the study may be extended for a further period to examine the longer-term impact of the use of lamotrigine on mental health of people with borderline personality disorder.

Who is funding the study?
National Institute for Health Research (UK): Health Technology Assessment programme

Who is the main contact?
Prof. Mike Crawford
m.crawford@imperial.ac.uk

Study website
www.labile.org

Contact information

Type(s)
Scientific

Contact name
Prof Mike Crawford

ORCID ID
http://orcid.org/0000-0003-3137-5772

Contact details
Centre for Mental Health
Imperial College London
Claybrook Centre
37, Claybrook Road
London
United Kingdom
W6 8LN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 10/103/01

Study information

Scientific Title
The clinical and cost effectiveness of lamotrigine for people with borderline personality disorder: a randomised controlled trial

Acronym
LABILE

Study objectives
The main aims of the study are:
1. To test whether adding lamotrigine to usual care for adults with borderline personality disorder (BPD) improves mental health over a 52 week period, in comparison to a placebo control.
2. To examine whether the addition of lamotrigine to usual care for adults with BPD improves social functioning and quality of life, reduces the incidence of suicidal behaviour, and lowers the amount of antipsychotic and other psychotropic medication that people are prescribed, in comparison to a placebo control.
3. To compare the incidence of side effects among those prescribed lamotrigine in addition to usual care for adults with BPD, in comparison to a placebo control.
4. To examine the cost, cost-utility and cost-effectiveness of adding lamotrigine to usual care for adults with BPD, in comparison to a placebo control.

The primary hypothesis is that the addition of lamotrigine to usual treatment of people with borderline personality disorder who are in contact with mental health services will reduce symptoms of their disorder measured at 12 months using the Zanarini Rating Scale for Borderline Personality Disorder.

More details can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/1010301/#/
Protocol can be found at: https://njl-admin.nihr.ac.uk/document/download/2006979

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Central Research Ethics Committee, ref: 12/LO/1514

Study design
Multi-centre two-arm parallel-group double-blind placebo-controlled randomised trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Borderline personality disorder

Interventions
1. Lamotrigine (oral, once daily, up to 200mg daily - unless the study participants is taking the combined oral contraceptive pill in which case the maximum daily dose will be 400mg daily)
2. Placebo (oral, once daily)

Follow-up assessment at 12, 24 and 52 weeks

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Symptoms of BPD measured at 52 weeks using the Zanarini Rating Scale for Borderline Personality Disorder (ZAN-BPD)

Secondary outcome measures
1. Total score on the Zanarini Rating Scale for Borderline Personality Disorder at 12 and 24 weeks
2. Depressive symptoms measured using the Beck Depression Inventory at 12, 24 and 52 weeks
3. The incidence and severity of suicidal behaviour using the Acts of Deliberate Self-Harm Inventory at12, 24 and 52 weeks
4. Social functioning assessed using the Social Functioning Questionnaire at 12, 24 and 52 weeks
5. Health-related quality of life, assessed using the Euro-QOL-5D (EQ-5D) at 12, 24 and 52 weeks
6. Side effects of trial medications using a proforma specifically designed for the study will be assessed at 12, 24, and 52 weeks
7. Resource use assessed using a modified version of the Adult Service Use Schedule at 12, 24 and 52 weeks
8. Body weight measured at 24 and 52 weeks

Overall study start date
01/11/2012

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. Age 18 and above
2. Fulfilling Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnostic criteria for borderline personality disorder
3. Competent and willing to provide written, informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
252 (126 in the active and 126 in the control arm of the trial)

Total final enrolment
276

Key exclusion criteria
1. Currently fulfilling criteria for bipolar affective disorder (type I & II), or psychotic disorder (schizophrenia, schizoaffective disorder, or mood disorder with psychotic features)
2. Already being prescribed a mood stabiliser(s)
3. Daily use of alcohol or illicit drugs during the previous three months
4. Known medical history of liver or kidney impairment
5. Cognitive or language difficulties that would preclude subjects providing informed consent or compromise participation in study procedures
6. Any woman who is pregnant or planning a pregnancy, and any woman of child bearing potential unless using adequate contraception

Date of first enrolment
01/11/2012

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
London
United Kingdom
W6 8LN

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
5th Floor, Lab Block
Charing Cross Hospital
Fulham Palace Road
London
England
United Kingdom
W6 8RF

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Health Technology Assessment Monograph – December 2017

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/07/2015		Yes	No
Results article	results	01/04/2018		Yes	No
Results article	results	01/08/2018	11/07/2019	Yes	No
HRA research summary			28/06/2023	No	No