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The EFFECT-Dep study: Enhancing the effectiveness of electroconvulsive therapy in severe depression

Submission date
16/06/2008

Recruitment status
No longer recruiting

Registration date
27/06/2008

Overall study status
Completed

Last Edited
26/05/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Electroconvulsive therapy (ECT) is used to treat severe mental disorders in 1.4 million people annually worldwide, with depression being the most common reason in Western countries. It involves sending an electric current through the brain via an electrode (sticky pad that conducts electricity) to cause a seizure in the brain that relieves mental health symptoms. Globally, depression is the second largest cause of years lived with disability and 30% of sufferers do not respond to antidepressant drugs and/or talking therapies. Available for more than 75 years, ECT continues to be the most effective treatment for severe, often treatment-resistant, depression. The most commonly used type of ECT is bitemporal ECT, in which one electrode is placed on each temple so that the whole brain is stimulated. This is thought to be more effective for treating depression that right unilateral (RUL) ECT, in which both electrodes are place on the right temple so only that side of the brain is stimulated, but it has more cognitive side-effects (problems with thought, memory and mental processing). Recent studies have suggested that, by increasing the electrical charge by above the seizure threshold (amount of electricity needed to cause a seizure), high-dose RUL ECT is as effective as bitemporal ECT but still causes its cognitive side-effects. These studies, however, were all effectiveness studies with limited follow-up and often small sample sizes in which regular antidepressant medications were stopped and ECT was given three times a week (more than the twice-weekly treatment usually given in many European and other countries), even though this level of treatment ECT is no more effective than twice-weekly treatment but makes cognitive side-effects worse. The aim of this study is to assess the effectiveness twice-weekly standard moderate dose (1.5 x seizure threshold) bitemporal electroconvulsive therapy (ECT) compared with high-dose (6 x seizure threshold) right unilateral (RUL) ECT at reliving depression as well as looking at the levels of cognitive side-effects caused.

Who can participate?
Adult patients with depression who have been referred for ECT.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a

course of standard (1.5 x seizure threshold) bilateral ECT. Those in the second group receive a course of high-dose (6 x seizure threshold) right unilateral ECT. Participants in both groups continue to recieve ECT until their depressive symptoms go away or until they have had 12 treatment sessions (whichever comes first). Participants complete a questionnaire to measure their depression levels at the start of the study and then after 3, 4, 6, 9 and 12 months. They also complete a number of tests and questionnaires to assess their memory function at the start of the study, around 4 days after their last ECT session and then after 3,6 and 12 months.

What are the possible benefits and risks of participating?
The main benefit of participating is helping to develop a more refined from of ECT that is just as good as the standard version but has less memory side-effects. Participants also benefit improving their knowledge about depression and its treatment. There are no additional risks associated with participation.

Where is the study run from?
1. St Patrick's University Hospital, Dublin (Ireland)
2. St Edmundsbury Hospital, Dublin (Ireland)
3. St James's Hospital, Dublin, (Ireland)

When is the study starting and how long is it expected to run for?
May 2006 to October 2014

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
Professor Declan McLoughlin
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01907217

Secondary identifying numbers
TRA/2007/5

Study information

Scientific Title
A randomised controlled trial comparing standard bilateral and high-dose unilateral electroconvulsive therapy for severe depression

Acronym
EFFECT-Dep

Study objectives
High-dose (6 x seizure threshold) right unilateral electroconvulsive therapy (ECT) is as effective as standard (1.5 x seizure threshold) bilateral ECT for severe depression but causes less cognitive side-effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Patrick's Hospital Research Ethics Committee, 08/10/2007, ref: 012/07

Study design
Single-centre double-blind randomised controlled non-inferiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Major depression

Interventions
Patients referred for bilateral ECT will be randomised to receive a course of either standard (1.5 x seizure threshold) bilateral ECT or high-dose (6 x seizure threshold) right unilateral ECT.

Patients will continue to receive ECT until they meet remission criteria (i.e. HDRS-24 score has declined by 60% or more from baseline score and is 10 points or less on two consecutive weekly assessments) or have received a maximum of 12 treatments. Patients will be followed-up for one year after the end of the ECT course.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The 24-item Hamilton Depression Rating Scale (HDRS) at end of allocated ECT treatment course, measured at baseline, at weekly intervals during the course of ECT, and about four days after the last ECT session. Thereafter, it will be measured every fortnight for eight weeks and at the following follow-up time points: 3, 4, 6, 9 and 12 months.

Secondary outcome measures
1. Measures of retrograde memory function at the end of allocated ECT treatment course
2. Autobiographical memory, measured using the Columbia Autobiographical Memory Interview-Short Form (AMI-SF)
3. Semantic memory, measured using a Famous Events Questionnaire

The secondary outcomes will be measured at baseline, about four days after the last ECT session, and at the following follow-up time points: 3, 6, and 12 months.

Overall study start date
01/05/2006

Completion date
31/10/2014

Eligibility

Key inclusion criteria
Participants in the trial will be patients greater than or equal to 18 years (either sex) with major depressive disorder (Diagnostic and Statistical Manual of Mental Disorders, fourth edition [DSM-IV]) and referred for ECT.

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
69 patients per group, i.e. a total of 138 patients (recuritment expected to be complete 31/12 /2012)

Key exclusion criteria
1. Any condition rendering patients medically unfit for general anaesthesia or ECT
2. Treatment with ECT in previous six months
3. Dementia or other axis 1 diagnosis
4. Alcohol/other substance abuse in previous six months
5. Inability/refusal to consent

Date of first enrolment
12/05/2008

Date of final enrolment
31/10/2012

Locations

Countries of recruitment
Ireland

Study participating centre
St Patrick's University Hospital
James's Street
Dublin
Ireland
8

Study participating centre
St Edmundsbury Hospital
Lucan
Dublin
Ireland
8

Study participating centre
St James's Hospital
James's Street
Dublin

Ireland
8

Sponsor information

Organisation
St Patrick's Hospital (Ireland)

Sponsor details
James's Street
Dublin 8
Ireland
8

Sponsor type
Hospital/treatment centre

Website
http://www.stpatrickshosp.ie/

ROR
https://ror.org/032e0fv91

Funder(s)

Funder type
Government

Funder Name
Health Research Board (HRB) (Ireland) (ref: TRA/2007/5)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016		Yes	No
Results article	results	08/03/2019		Yes	No
Results article	results	01/02/2021	16/02/2021	Yes	No
Results article		01/05/2021	26/05/2021	Yes	No