

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

<b>Submission date</b> 16/06/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/05/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 than right unilateral (RUL) ECT, in which both electrodes are placed 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 of 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 relieving 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 receive 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 form of ECT that is just as good as the standard version but has less memory side-effects. Participants also benefit from 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

Prof Declan McLoughlin

### Contact details

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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 (recruitment 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?
<a href="#">Results article</a>	results	01/04/2016		Yes	No
<a href="#">Results article</a>	results	08/03/2019		Yes	No
<a href="#">Results article</a>	results	01/02/2021	16/02/2021	Yes	No
<a href="#">Results article</a>		01/05/2021	26/05/2021	Yes	No