

# Clinical effectiveness and cost of repetitive transcranial magnetic stimulation versus electroconvulsive therapy in severe depression: a multi-centre randomised controlled trial and economic analysis

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
25/04/2003	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
25/04/2003	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
25/11/2010	Mental and Behavioural Disorders	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

HTA 98/11/04

# Study information

## Scientific Title

Investigating if repetitive transcranial magnetic stimulation (rTMS) was as effective as electroconvulsive therapy (ECT) in treating major depressive episodes and performing a cost-effectiveness analysis.

## Study objectives

1. To carry out a multi-centre Randomised Controlled Trial (RCT), with 6 months follow-up, of repetitive Transcranial Magnetic Stimulation (rTMS) versus Electroconvulsive Therapy (ECT) in patients with severe depression. Ninety patients will be entered into each arm of the trial, sufficient to obtain a 95% confidence interval to demonstrate equivalence or a subtle difference between rTMS and ECT. The objectives are:
  - 1.1. To determine if rTMS is as effective as ECT
  - 1.2. To determine if rTMS is associated with fewer side effects than ECT
  - 1.3. To identify patient characteristics indicative of a beneficial response to rTMS
  - 1.4. To ascertain patient preference for rTMS or ECT
2. To carry out a cost-effectiveness analysis of the use of rTMS versus ECT. The objectives are:
  - 2.1. To calculate the short and longer term costs of treatment with both rTMS and ECT
  - 2.2. To establish if there are any economic, as well as therapeutic, advantages in the use of rTMS compared to ECT in both the immediate and long term

Please note that, as of 16 January 2008, the start and end date of this trial have been updated from 1 May 2001 and 30 April 2004 to 1 August 2001 and 30 April 2005, respectively.

## 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

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Depression, anxiety, neuroses

## Interventions

1. Repetitive Transcranial Magnetic Stimulation (rTMS)
2. ECT

## Intervention Type

Other

**Phase**

Not Specified

**Primary outcome(s)**

The following will be used to obtain baseline, intra-treatment and follow-up data as appropriate:

1. The Hamilton Rating Scale for Depression, Visual Analog Mood Scale, Brief Psychiatric Rating Scale
2. Treatment side-effects and adverse events inventories
3. Cambridge Cognitive Examination (CAMCOG) plus specific tests of memory and frontal-executive function
4. Client Service Receipt Inventory and attendant methodologies for estimating unit costs of services and costs of treatment/care packages falling to the family and the NHS

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

30/04/2005

## Eligibility

**Key inclusion criteria**

All in-patients referred for ECT with severe depressive episodes (Diagnostic Research Criteria [DCR-10]), including patients refractory to standard medical/psychological treatments

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Not Specified

**Key exclusion criteria**

1. Age under 18 years
2. Evidence of dementia
3. History of substance misuse in previous 6 months
4. Schizophrenia or other functional psychosis
5. History of epilepsy or recent Cardiovascular Accident (CVA)/Myocardial Infarction (MI)/cardiac failure
6. Medically unfit to receive anaesthetic
7. Electronic and metallic implants or foreign bodies
8. Raised intracranial pressure
9. Inability to provide informed consent

**Date of first enrolment**

01/08/2001

**Date of final enrolment**

30/04/2005

## Locations

**Countries of recruitment**

United Kingdom

Ireland

**Study participating centre**

Department of Psychiatry

Dublin

Ireland

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## Sponsor information

**Organisation**

Department of Health (UK)

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

## Results and Publications

**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?
<a href="#"><u>Results article</u></a>	results	01/01/2007		Yes	No
<a href="#"><u>Other publications</u></a>	HTA monograph	01/07/2007		Yes	No