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

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
25/11/2010

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2001

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

Age group
Adult

Sex

Not Specified

Target number of participants
46 enrolled

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
Ireland

United Kingdom

Study participating centre
Department of Psychiatry
Dublin
Ireland
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
Quarry Hill
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LS2 7UE
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Sponsor type
Not defined

Website
http://www.dh.gov.uk/en/index.htm

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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	01/01/2007		Yes	No
Other publications	HTA monograph	01/07/2007		Yes	No