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Reducing adverse electroconvulsive treatment effects on memory by magnetic stimulation

Submission date
19/04/2006

Recruitment status
Stopped

Registration date
07/06/2006

Overall study status
Stopped

Last Edited
06/10/2009

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Klaus Ebmeier

Contact details
Kennedy Tower
Morningside Park
Edinburgh
United Kingdom
EH10 5HF
+44 (0)131 5376505
k.ebmeier@ed.ac.uk

Additional identifiers

Protocol serial number
G0401083

Study information

Scientific Title

Study objectives

We propose a two-year pilot randomised controlled trial of electroconvulsive treatment (ECT) versus magnetic seizure therapy (MST) in 80 Edinburgh patients recruited from 100 new treatment courses started per year in Edinburgh (75 after giving informed consent) to examine the following questions:
1. Is MST less liable than ECT to cause anterograde and retrograde memory impairment and what is the likely size of the effect?
2. Is MST equally effective to ECT within the power of a moderately large randomised study with blind evaluation of symptom change?
3. Is MST more user-friendly and user-acceptable than ECT?
4. What is the balance of cost versus benefit comparing ECT and MST in patients referred for ECT?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval not yet received as of 07/06/06

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Memory impairment

Interventions
1. Randomisation to either ECT or MST groups
2. ECT protocol (treatment as usual): ECT will be administered in line with the latest guidelines from the Royal College of Psychiatrists. Seizure threshold will be measured at the outset of treatment, bilateral ECT given with a dose 50% above threshold, and right unilateral ECT given with a dose initially 300% above threshold. Treatment will be given with a modern constant current ECT machine using doses of 100-400 mC (mode = 150 mC, 800 mA, 20-120 Hz; pulse width 1 ms; MECTA Spectrum™ 5000 M), and monitored by electroencephalogram (EEG). The clinical team responsible for the patient will determine the need for and duration of treatment, usually between 6 and 12 treatments.
3. MST protocol: MST will be administered mirroring the dose titration process above. Prefrontal coil placement will be used with a stimulation frequency between 50 and 100 Hz at various output strengths. Seizures will be monitored using EEG (split electrodes to prevent heating). The clinical team responsible for the patient will determine the need for and duration of treatment, usually between 6 and 12 treatments. The responsible team can request exit from the protocol and transfer to ECT, if there are clinical concerns, such as deterioration or emerging suicidality.

Added 06/10/09: the trial was stopped due to participant recruitment issues.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Last follow-up six months after course of treatment of last recruited subject recruited before 31st March 2008 or 80th subject recruited

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/05/2008

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Referred to and accepted by ECT service for treatment of major depressive episode
2. Able to give informed consent to ECT and to trial procedure
3. If patient is detained, ECT would be given with patient's consent (valid T2 form completed)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Contraindications for ECT or anaesthesia
2. Unable or unwilling to give informed consent to ECT or to trial procedure
3. Patients with organic diagnoses (e.g. dementia, schizophrenia and substance abuse)
4. Patients with metallic implants or pacemakers
5. Pregnancy
6. Aged <18 years

Date of first enrolment
01/04/2006

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Kennedy Tower
Edinburgh
United Kingdom
EH10 5HF

Sponsor information

Organisation
University of Edinburgh (UK)

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
The Medical Research Council (MRC) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration