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# Reducing adverse electroconvulsive treatment effects on memory by magnetic stimulation

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 19/04/2006 | Stopped | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 07/06/2006 | Stopped | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 06/10/2009 | Signs and Symptoms | [ ] Record updated in last year |

**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**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
Last follow-up six months after course of treatment of last recruited subject recruited before 31st March 2008 or 80th subject recruited

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/04/2006

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
2 x 40

### 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
Scotland

United Kingdom

### Study participating centre
**Kennedy Tower**
Edinburgh
United Kingdom
EH10 5HF

## Sponsor information

### Organisation
University of Edinburgh (UK)

### Sponsor details
The University of Edinburgh
Old College
South Bridge
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United Kingdom
EH8 9YL

### Sponsor type

University/education

**Website**
http://www.ed.ac.uk/contact.html

**ROR**
https://ror.org/01nrxwf90

# Funder(s)

**Funder type**
Government

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