

Randomised controlled trial of electroconvulsive therapy (ECT) with pharmacotherapy or pharmacotherapy alone in relapse prevention of depression

Submission date 21/06/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 16/07/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/02/2019	Condition category 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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00627887

Protocol serial number
070621

Study information

Scientific Title

Randomised controlled trial of electroconvulsive therapy (ECT) with pharmacotherapy or pharmacotherapy alone in relapse prevention of depression

Study objectives

Current hypothesis as of 21/12/2007:

Electroconvulsive therapy (ECT) and pharmacotherapy combined is more effective than pharmacotherapy alone.

Previous hypothesis:

Electroconvulsive therapy (ECT) and pharmacotherapy combined is more efficient than pharmacotherapy alone and ECT alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee in Uppsala (Sweden), 28/11/2007, ref: Dnr 2007/301

Study design

Randomised controlled trial with two parallel groups

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Major depressive disorder

Interventions

Current interventions as of 25/07/2008:

The patients will have ECT three times weekly in the index series (before the trial).

ECT: During the trial the patients have unilateral ECT weekly for the first six weeks then every other week for 46 weeks.

Pharmacotherapy: Pharmacotherapy will include treatment with venlafaxine target dose 300 mg /d within the first four weeks combined with lithium dosed according to serum-concentration 0.5 - 0.8 mmol/L.

Previous interventions:

The patients will have ECT three times weekly in the index series (before the trial).

ECT: During the trial the patients have unilateral ECT weekly for the first six weeks then every other week for 46 weeks.

Pharmacotherapy: Pharmacotherapy will include treatment with venlafaxine target dose 300 mg /d within the first four weeks combined with lithium dosed according to serum-concentration 0.5 - 0.9 mmol/L.

Intervention Type

Mixed

Primary outcome(s)

Relapse, defined as either:

1. Rehospitalisation in a psychiatric ward, or
2. More than 20 on the MADRS interview. MADRS-S self-assessment is provided weekly for the first six weeks then every other week.

Key secondary outcome(s)

Current secondary outcome measures as of 21/12/2007:

1. Memory problems measured with:
 - 1.1. Mini Mental State Examination (MMSE)
 - 1.2. Alzheimer Disease Assessment Scale-cognitive subscale (ADAS-cog)
 - 1.3. At one site the Autobiographical Memory Inventory Short Form will also be used
2. Medication Side-effects measured with the Udvalg for Kliniske Undersogelser (UKU) Side Effect Rating Scale

Patients are assessed at 2 months, 6 months and 12 months after randomization and at relapse.

Previous secondary outcome measures:

1. Side-effects measured with the Udvalg for Kliniske Undersogelser (UKU) Side Effect Rating Scale self-assessment
2. Memory problems measured with Mini Mental State Examination (MMSE), Squire Subjective Memory Questionnaire and the Autobiographical Memory Inventory Short Form
3. Quality of life is measured with 36-item Short Form health survey (SF-36)

Patients are assessed after 2 months, 6 months and 12 months and at relapse.

Completion date

31/12/2010

Eligibility

Key inclusion criteria

Current inclusion criteria as of 25/07/2008:

1. Mini International Neuropsychiatry Interview Plus (MINI-PLUS) verified major depressive episode (unipolar or bipolar)
2. ECT within the last 3 weeks
3. Either remission defined as Montgomery-Asberg Depression Rating Scale (MADRS) less than 10, or
4. Response defined as MADRS less than 15 combined with patient assessed Clinical Global Impressions-Improvement Scale (CGI-I) of at least much improved

Previous inclusion criteria:

1. Patients treated with ECT for Diagnostic and Statistical Manual of mental disorders - Fourth Edition (DSM-IV-TR) diagnosis of major depression

2. Remission (less than 10 on the Montgomery-Asberg Depression Rating Scale [MADRS])
3. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Current exclusion criteria as of 25/07/2008:

1. Schizophrenia or schizoaffective disorder
2. Addiction or dependence
3. Kidney disease that contraindicates lithium treatment
4. Vascular or heart disease that contraindicates venlafaxine treatment
5. Uncontrolled epilepsy
6. Aged less than 18 years
7. Pregnancy or lactation

Previous exclusion criteria:

1. Bipolar 1 disorder
2. Schizophrenia and schizoaffective diagnosis
3. Abuse or dependence diagnosis
4. Kidney disease
5. Heart disease
6. Epilepsia
7. More than three weeks since index ECT
8. Under 16 years of age, more than 10 on the MADRS after 12 index ECT

Date of first enrolment

15/01/2008

Date of final enrolment

31/12/2010

Locations**Countries of recruitment**

Sweden

Study participating centre

Universitetsjukhuset Örebro
Örebro

Sweden
70185

Sponsor information

Organisation

Orebro County Council (Orebro l ns landsting) (Sweden)

ROR

<https://ror.org/00maqj547>

Funder(s)

Funder type

Government

Funder Name

Regional Research Council of the Uppsala-Orebro Region (Regionala forskningsradet i Uppsala-Orebro regionen) (Sweden)

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?
Results article	results	01/06/2013	14/02/2019	Yes	No