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

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
21/06/2007		∐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
16/07/2007		[X] Results		
<b>Last Edited</b> 14/02/2019	<b>Condition category</b> Mental and Behavioural Disorders	Individual participant data		

## Plain English summary of protocol

Not provided at time of registration

## Contact information

# Type(s)

Scientific

#### Contact name

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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-assemessment
- 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

Αll

## 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 epilepsia
- 6. Aged less that 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 Orebro

Örebro

# Sponsor information

## Organisation

Orebro County Council (Orebro lans 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes