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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

Registration date
16/07/2007

Overall study status
Completed

Last Edited
14/02/2019

Condition category
Mental and Behavioural Disorders

[X] 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
NCT00627887

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
15/01/2008

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

Age group
Adult

Sex
Both

Target number of participants
100

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
Sweden
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Sponsor information

Organisation
Orebro County Council (Orebro lans landsting) (Sweden)

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Sponsor type
Government

Website
http://www.orebroll.se/uso/page____2834.aspx

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

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	01/06/2013	14/02/2019	Yes	No