Mood Disorders in Elderly and ECT (Electroconvulsive therapy): Electroconvulsive therapy can induce brain derived neurotrophic factor in serum and increase cortisol levels to enhance neurorestorement of hippocampal volume and function.

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To predict and evaluate the effectively and safety of ECT in depressed elderly.1. the relation between clinical parameters and the safety and effectively of ECT in elderly with a severe depressive disorder2. the relation between structural brain...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Observational invasive

Summary

ID

NL-OMON47034

Source
ToetsingOnline

Brief title
MODECT

Condition

- Mood disorders and disturbances NEC

Synonym
psychotic depression, severe depression

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: database, depressive disorder, elderly, electroconvulsive therapy

Outcome measures

Primary outcome

clinical parameters predict safety and effect of ECT

MRI findings predict safety and effect of ECT

lack of cortisol response predicts response to ECT

BDNF increases after ECT and there is neurorestorement of hippocampal volume

genetic profile predicts clinical parameters and effect of ECT

Secondary outcome

there are no secundary study parameters

Study description

Background summary

Depressive disorders are more frequent in the elderly and have a poor prognosis in terms of chronic or remittent course, co-morbidity with somatic diseases, functional impairments and cognitive disorders, and increased mortality rates. Therefore, insight in symptoms and prognosis of depressive disorder in the elderly is of great importance. Several studies have shown that severe depression with psychomotor, psychotic or vital symptoms are best treated with tricylcic antidepressants (TCA) or ECT (Parker 2007). Identifying patients that will respond to ECT will enable earlier conversion to TCA or ECT in de treatment of depression. This is of great importance since longer index episode predict worse outcome and early intervention may limit the number of ECT

sessions needed and thereby limit side-effects.

In January 2010 we will start on the ward with the systematic collection of data on the patients treated with ECT. This is care as usual. The data will collected anonymously and systematic for future analysis.

Study objective

To predict and evaluate the effectively and safety of ECT in depressed elderly.

1. the relation between clinical parameters and the safety and effectively of ECT in elderly with a severe depressive disorder
2. the relation between structural brain abnormalities with MRI and the safety and effectively of ECT in elderly with a severe depressive disorder
3. the relation between neuro-endocrine parameters and the safety and effectively of ECT in elderly with a severe depressive disorder
4. the relation between genetic profile and effectively of ECT in elderly with a severe depressive disorder

Study design

Patients included in the systematic and anonymously data of patients treated with ECT will be asked to participate. They will be asked to give a separate informed consent for the blood and saliva samples. 80 patients of 60 years and over admitted to the clinical psychiatric ward with a severe depression, confirmed by the MINI, will be asked to participate.

Patients will be informed by the psychiatrist or research assistant about the research, written information will be given as well and patients will be asked for a written informed consent.
Appointments for sample collection will be scheduled. Patients can participate for blood, saliva or both.

BDNF
Blood (5cc, 1 tube) will be drawn, combined with blood draws indicated by the clinic. There are 4 time-points, T0 before ECT, T1 after 6 ECT sessions, T2 after the last ECT session and T4 6 weeks after the last ECT session. In several studies it was shown that BDNF was low in severely depressed patients before treatment (T0) and increased after treatment (T3). The time-point T1 and T2 are to possibly identify BDNF as predictor of response to ECT.

Genetic profile.
Blood will be drawn for BDNF, once red blood cells will be stored for genetic profiling.

Cortisol

As a indicator of the stress response of the hypothalamic-pituary-adrenal axis the morning curve cortisol is determined (Vreeburg et al, 2009) with saliva samples at awakening, after 30 , 45 and 60 minutes (Wust et al. 2000) and the circadian rhythm (additional sample at 22 en 23 hours). Saliva is collected by chewing on cotton cloths. Saliva will be extracted from the cloths and stored at -85*C for future research. Saliva will be collected at two time points, before ECT (T0) and after the last ECT (T2).

Study burden and risks

The patients included are admitted with a severe mood disorder, therefore the nature and extent burden for the participants will be limited. Blooddraws will be combined with blooddraws indicated by the treating psysician as part of patient care. The cortisol measurements will include chewing on cotton supplied by the nurse on the ward and are with little burden in the patient. None of the interventions are of potential risk for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

severe depression conform DSM IV criteria egible for electroconvulsive therapy, inpatient, 60 years and older

Exclusion criteria

dementia, younger than 60 years
severe neurological disorder
incapacity to give informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2011
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2010
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-02-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL31041.029.10