Pathophysiology of therapeutic and cognitive side-effects of Electroconvulsive Therapy (ECT).

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1. To investigate neuropsychological deficits during an ECT course in relationship to cortisol levels 2. To investigate the underlying neural correlates, i.e. functional connectivity, structural connectivity, and amygdala reactivity, that are...

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

Summary

ID

NL-OMON30867

Source
ToetsingOnline

Brief title
(Patho)physiological mechanisms of ECT

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognition, Diffusion Tensor Imaging (DTI), Electroconvulsive Therapy (ECT), functional Magnetic Resonance Imaging (fMRI)

Outcome measures

Primary outcome

- Mood (categorical DSM-IV diagnose, severity assessed with observer rated questionaire)

- A detail neuropsychological examination (focus on memory and executive functioning).

- Neuroimaging, i.e. functional connectivity (fMRI), structural connectivity (DTI), and amygdale reactivity (fMRI: Hariri paradigm)

- Hypothalamic-pituitary-adrenal axis functioning (dexamethason suppression test) by nine cortisol measures in saliva.

Secondary outcome

N.A.

Study description

Background summary

Electroconvulsive therapy (ECT) is the most effective treatment for depressive disorder, although the underlying mechanisms are poorly understood. Moreover, patient and clinical acceptance are limited by significant cognitive side-effects.

Study objective

1. To investigate neuropsychological deficits during an ECT course in relationship to cortisol levels
2. To investigate the underlying neural correlates, i.e. functional connectivity, structural connectivity, and amygdala reactivity, that are

involved in successful electroconvulsive treatment of depression.

Study design

Observational study of patients who receive ECT will be assessed additionally before and after the ECT course.

Study burden and risks

In addition to the normal procedure and measures for ECT treatment, an additional burden will be placed on patients due to the neuroimaging part (estimated at 20 minutes), a detailed neuropsychological testing (estimated at 60 minutes), and 9 cortisol measures in saliva, incl. one after 0.5 mg dexamethason ingestion, before and after ECT. The risks for these additional measurements are almost nihil.

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

- Males and females above 18 years of age
- Unipolar major depressive disorder with and without psychotic features, first and recurrent episode

Exclusion criteria

- Presence of a current or past relevant somatic or neurological disorder
- Comorbid diagnosis of bipolar depression, schizophrenia or substance dependence.
- MRI-related exclusion criteria like claustrophobia, metal in body, pacemaker, pregnancy, etc.
- ECT course within the past year
- Use of antidepressants (according to good clinical practice, antidepressants have to be withdrawn before an ECT course, so this will not be a major issue).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL17318.091.07