Study on Neuroimaging predictors of Outcome in ECT Patients

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

Summary

ID

NL-OMON43040

Source
ToetsingOnline

Brief title
SNOEP

Condition

- Mood disorders and disturbances NEC

Synonym
Bipolair depression, Depression, Major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Rijnland Ziekenhuis
Source(s) of monetary or material Support: Jeroen A van Waarde voor Psychiatrie en Psychotherapie BV;BdePont Praktijk BV

Intervention

Keyword: Depression, ECT, EEG, MRI

Outcome measures

Primary outcome

Primary Objectives:

Our primary objective is to predict antidepressant response to ECT for

individual patients using EEG and fMRI data.

Secondary outcome

Secondary Objectives:

The first secondary objective is to predict cognitive side-effects of ECT for

individual patients using EEG and fMRI data. Also, as secondary objective the

possible change in EEG and fMRI data directly after a course of ECT and at

follow-up will be explored.

Study description

Background summary

Severe depressive symptomatology occurs commonly in the population and is associated with significant functional impairment. Depressive symptomatology is seen in unipolar major depressive disorder (MDD) and bipolar disorder, type 1 as well as type 2. Many depressed patients can be treated successfully with antidepressants, moodstabilizers such as lithiumcarbonate and/or psychotherapy. However, the largest clinical trial in the United States showed that at least one third of the patients do not recover even after four successive steps of pharmacological/psychotherapeutic treatment, and that 21% of depressed patients meet the criteria for chronic depression (duration longer than 2 years) (Rush et al., 2006). Electroconvulsive therapy (ECT) is an important treatment option for such medication resistant patients; depending on the response criteria, about 40-60% of these resistant patients recover (Prudic et al., 1996; van den Broek, de Lely, Mulder, Birkenhager, & Bruijn, 2004). However, this implies that approximately 50% of these patients do not respond or respond

insufficiently. Furthermore, of the patients who initially recover on ECT, 40-80% relapse within half a year, which is in part dependent on the type of continuation treatment given after ECT (Sackeim et al., 2001).

Predicting treatment outcome using neuroimaging techniques
Previous studies have shown that neuroimaging might be used to predict treatment outcome. Functional magnetic resonance imaging (fMRI) and quantitative electroencephalogram (qEEG) have been used to predict treatment outcome to various antidepressant treatments at group level (for review see: Arns & Olbrich, 2014; Pizzagalli, 2011) such as antidepressants (Arns et al., 2015a, 2015b), rTMS (Arns et al., 2012) and ECT (ten Doesschate et al., 2014). Furthermore, the cognitive side-effects of ECT have also been related to EEG parameters at group level (Sackheim et al., 2000; Ten Doesschate et al, 2015). However, these methods only allow inferences to be made at group level, limiting the ability to use these findings in the clinical practice. Recent advances in neuroscientific analysis techniques opened up the possibility of predicting treatment outcome for individual patients and has potential to serve as prognostic biomarkers to guide personalized treatment decisions. That is, in a previous study using a machine learning approach, achieving remission after ECT was accurately predicted by analyzing pre-treatment fMRI data (J. Van Waarde et al., 2015). Similar findings have been reported using fMRI in smaller samples for antidepressant pharmacotherapy (Fu et al., 2008; Korgaonkar et al., 2014) and cognitive behavioural therapy in depression (Costafreda et al., 2009). Other studies predicted the treatment outcome of rTMS and pharmacotherapy using a machine learning approach to EEG data (Erguzel et al., 2015; Khodayari-Rostamabad et al., 2013).
Although the use of neuroimaging as a prognostic biomarker in the treatment of depression seems promising, findings need to be replicated and extended before they can be put into clinical practice.

Study objective

The primary objective of this study is to predict the antidepressant treatment outcome of ECT in patients with severe depressive symptomatology using neuroimaging. ECT itself is conducted as usual according to national guidelines (Nederlandse Vereniging voor Psychiatrie, 2010). fMRI and EEG resting-state data will be acquired within two weeks prior to initiation of the ECT course. A machine learning approach will be used to predict remission rates. Thereby, we replicate one of our previous studies in which we successfully predicted ECT outcome using fMRI (J. Van Waarde et al., 2015). Furthermore, we aim to extend these findings using EEG data. Compared to fMRI, EEG data can be acquired at lower costs and the equipment for EEG acquisition is more widely available throughout psychiatric clinics. Thereby, taking a machine learning approach to EEG data bears great potential to become a widely used prognostic biomarker for the prediction of ECT outcome.
The second objective of this study is to predict the cognitive side-effects of ECT for individual patients. The ability to predict the potential cognitive

side-effects, weighted to the expected antidepressant efficacy, of ECT may guide physicians and patients in determining the best course of treatment. Finally, because ECT seems to change brain functioning, after a course of ECT the neuroimaging parameters are repeated to explore for changes due to treatment and at a follow-up period of three months after ECT.

Study design

We will use a prospective cohort design following a group of severely depressed patients, indicated for a course of ECT. Depressive symptoms and cognitive measures will be established at pre-ECT baseline and post-ECT endpoint. BDI-II depression scales will be established biweekly, if the patient is capable to do so. MRI and EEG measures will be performed at pre-ECT baseline, as well as after the index-course of ECT (endpoint) and after three months (follow-up).

Study burden and risks

The burden of ineffectively treated depression is high. The burden of ECT is considerable but is warranted because of successful
treatment, and its risk can be considered negligible. Importantly, only the regular ECT-population will be recruited. The additional
burden for participating in this study is minimal and the additional risk negligible. The additional
burden for participating in the neuroimaging study can be considered minimal, and the additional risk for eligible candidates is
negligible.

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

- Major depressive disorder (MDD) or depressed bipolar disorder, with or without psychotic symptoms
- Clinical indication for ECT
- 18 years or older

Exclusion criteria

- Schizophrenia, primary alcohol or drug abuse, or any cognitive disorder

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2016

Enrollment:	336
Type:	Actual

Ethics review

Approved WMO Date:	06-07-2016
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	NL56784.091.16