Factors influencing seizure threshold in Electroconvulsive Therapy

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1. To determine demographic, clinical, and brain morphological and functional predictors for IST, and; 2. To examine their associations with the level of increase of seizure threshold (*ST) during the ECT course, as measured at every sixth ECT-...

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

Summary

ID

NL-OMON33666

Source
ToetsingOnline

Brief title
Factors influencing IST

Condition

- Mood disorders and disturbances NEC

Synonym
depression, depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Alysis Zorggroep
Source(s) of monetary or material Support: eigen investering van onderzoekers (tijdsbesteding)

Intervention

Keyword: Electroconvulsive Therapy, predictors, seizure threshold

Outcome measures

Primary outcome

a. Level of IST and level of seizure threshold at every 6th ECT-session;

b. Thickness of the skull and scalp; volume and amount of white matter hyperintensities (WMH); cortical thickness; volumes of gray and white matter; and volume of cerebrospinal fluid (CSF) using magnetic resonance imaging (MRI);

c. Resting state functional connectivity using blood oxygen level-dependent signals (BOLD) on functional MRI (fMRI) of specific areas;

d. Amount of axonal density (*fractional anisotropy*) as measured with Diffusion Tensor Imaging (DTI) of specific areas.

Secondary outcome

The association between IST, *ST, demographic, clinical, and brain morphological and functional predictors and effectiveness of ECT.

Study description

Background summary

Electroconvulsive therapy (ECT) is an effective and safe treatment for depression, as well as for other severe psychiatric conditions. In ECT, the electrical stimulus must exceed the initial seizure threshold (IST) to elicit a generalized seizure. Clinically it is known that seizure thresholds vary substantially among patients and seizure thresholds intend to raise during the treatment course. Several hypothesis are described to explain the variety of IST levels in patients, but most hypotheses on morphologically, functionally and clinically influencing factors were neither examined extensively nor studied prospectively for this purpose.

Study objective

1. To determine demographic, clinical, and brain morphological and functional predictors for IST, and;
2. To examine their associations with the level of increase of seizure threshold (*ST) during the ECT course, as measured at every sixth ECT-session.

Study design

Prospective, observational, cohort study.

Study burden and risks

Every subject undergoes standard procedures (ECT, dose-titration, MRI) and the extra burden for the patient for this study are within reasonable limits (i.e. 10-15 minutes extra time in the MRI-scanner). No additional risks for the patients health are expected with this study. If coincidentally pathological findings will be present, further treatment strategies will be discussed by the consulted neurologist and treating psychiatrist.
This research may result in non-invasive measurement of IST in advance, and therefore future patients may benefit, as the first treatment session will not has to be used for dose-titration and ECT will start immediately with a therapeutic electrical dose.

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

The sample of subjects contains all patients referred for ECT to the Alysis Zorggroep, location Rijnstate Hospital, Arnhem, the Netherlands

Exclusion criteria

a. age < 18 years;
b. no informed consent;
c. contraindications for dose-titration (e.g. life threatening condition of the patient, severe cardiovascular comorbidity);
d. contraindication for undergoing MRI (e.g. metals in the body, claustrophobic reactions, patient cannot lay still).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2009

Enrollment:	60
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	28-04-2009
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	NL24697.091.09