Understanding the Efficacy of Electroconvulsive Therapy in Patients with Unipolar and Bipolar Depression

Published: 03-09-2013
Last updated: 24-04-2024

This study aims to investigate the neurobiological basis underlying the strong antidepressant effect of ECT in patients with unipolar and bipolar depression using MRI. We will also assess a potential neurobiological basis for the cognitive side-...

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

Summary

ID

NL-OMON40130

Source
ToetsingOnline

Brief title
The Efficacy of ECT in Patients with Depression

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, Depressive Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Aspasia Grant

Intervention

Keyword: Angiogenesis, Electroconvulsive Therapy, Hippocampus, Major Depression

Outcome measures

Primary outcome

The main study parameter is the change in volume of hippocampal subdivisions.

Vessel permeability, vessel size and density parameters will also be assessed .

Changes in hippocampal blood vessel characteristics and volumes of hippocampal subdivisions are associated to clinical recovery from depression (changes in HAM-D score >50%).

Secondary outcome

1. A potential neurobiological basis for the cognitive side-effects of ECT will be assessed by screening all patients prior and after ECT for subtle tissue changes in grey and white matter brain structures and associating these to the severity of cognitive side-effects as measured by a battery of cognitive tests.

2. To compare pre- and posttreatment inflammatory, immunologic, genomic and proteomic markers in blood of patients treated with ECT and associate these to clinical recovery from depression.

3. To compare efficacy of ECT in patients with unipolar versus bipolar depression, as well as differences in values of vascularisation and volumes of subsections of the hippocampus.

Study description

Background summary

Electroconvulsive therapy (ECT) is the oldest and most effective therapy in major depressive disorder (MDD). However, its mechanism of action is still unresolved. Recent evidence suggests that the efficacy of pharmacotherapy and psychotherapy in MDD has been overstated with effect sizes considerably lower than previously claimed (0.3) while ECT has an estimated effect size of 1.0. Nevertheless, ECT carries all the risks of general anaesthesia and is associated with (severe) cognitive impairment. Therefore, understanding the mechanism of action of ECT is a necessary step in the development of new safer treatment methods for MDD. Animal studies showed that ECT induces angiogenesis and neurogenesis in the dentate gyrus of the hippocampus. It is currently unclear if these findings can be translated to patients with MDD. By investigating the structural changes in the hippocampus of patients with unipolar and bipolar depression treated with 10 ECT sessions we intend to elucidate the working mechanism of ECT.

Study objective

This study aims to investigate the neurobiological basis underlying the strong antidepressant effect of ECT in patients with unipolar and bipolar depression using MRI. We will also assess a potential neurobiological basis for the cognitive side-effects of ECT, assess the immunologic and inflammatory parameters in patients pre- and post-ECT, and collect data on genomics. We will try to correlate these to clinical recovery and cognitive side-effects. Moreover, efficacy of ECT in patients with unipolar versus bipolar depression is compared.

Study design

The objectives are tested in a controlled observational trial using MRI scanning, blood samples for inflammatory and immunologic assessment and proteome based biomarkers and genomics, and cognitive testing to assess cognitive side-effects.

Study burden and risks

Additional to the risks generally associated with ECT (such as cognitive impairment and risks associated with general anaesthesia) which are not due to participation, there are only minor risks. Lying in the MRI scanner (estimated time maximum of 50 minutes) may trigger claustrophobia and discomfort in some participants. Participants are accompanied by an experienved researcher or research nurse. To make the procedure as comfortable as possible, participants

are provided with pillows and earplugs or headphones (to listen to music). Contrast is not used, and subjects are not asked to perform any tasks. Vene puncture may cause haematoma or infection. Cognitive testing (1.5 hour) may require sustained attention of the participant. The burden consists of 4 hours at t1 (M.I.N.I.-plus, HAM-D, MRI-scan, cognitive assessment, blood), 3 hours at t2 (HAM-D, MRI-scan, cognitive assessment, blood), and 2 hours at t3 (6 months follow-up: HAM-D and cognitive assessment). Burden for healthy controls will be 4 hours at visit 1 (M.I.N.I.-plus, MRI-scan, blood, cognitive assessment) and 2.5 hours at visit 2 (cognitive assessment and MRI-scan).

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients only:

- Diagnosis of depressive disorder according to the DSM-IV-TR criteria, either unipolar or bipolar
- Indication for electroconvulsive therapy;All subjects:
- Written informed consent
- Age 18 years and older

Exclusion criteria

All subjects:
- Severe cognitive impairments (Alzheimer's disease, vascular dementia)
- Pregnancy and/or lactation
- Not legally capable / not of sound mind and judgement;Patients only:
- ECT in the past 6 months;Controls only:
- Any psychiatric illness (according to the M.I.N.I.-plus interview)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2014
Enrollment:	124
Type:	Actual

Ethics review

Approved WMO

Date:	03-09-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL43935.041.13