Minder hinder na een epileptische aanval

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26656

Source
NTR

Brief title
SYNAPSE

Health condition

Epilepsy
Electroconvulsive therapy
Postictal state
Acetaminophen
Nimodipine
Hypoperfusion

Epilepsie
Elektroconvulsietherapie
Postictale fase
Paracetamol
Nimodipine
Hypoperfusie

Sponsors and support

Primary sponsor: University of Twente, Enschede; Rijnstate Hospital, Arnhem
Source(s) of monetary or material Support: Epilepsiefonds

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be ‘time to EEG normalization’, defined as the time interval between seizure onset and return to the pre-ECT (baseline) EEG, quantified with the temporal Brain Symmetry Index. This is a well-defined, robust and generally accepted quantitative metric of EEG background evolution over time.

Secondary outcome

• Clinical measures

o ‘Orientation recovery time’, defined as the time-interval between seizure onset and orientation in time, person, and place. Orientation recovery time will be tested at the bedside by the Reorientation Time list (ROT) every five minutes. This measure has shown to be a good discriminator in studies on ECT settings and a good predictor of long-term memory deficits.

o The incidence and severity of headache, nausea and myalgia as measured using a visual analogue scale. The inquiry will be performed at the first moment of full orientation, as measured by the ROT.

• EEG measures

o The alpha/delta ratio derived from the EEG as a function of time after ECT. This ratio will be fitted to a sigmoid function, allowing to extract the ‘postictal recovery time constant (PRTC)’.

o The cerebral recovery index (CRI) which is based on the evolution of several qEEG features over time and showed good discrimination between patients with good and poor recovery after global cerebral ischemia.

• MRI measures within one hour after seizure termination. Patients will undergo one MRI scan per condition. Regions of interest in cortex, cerebellum, white matter and hippocampus will be analyzed. We will use the following MRI sequences to answer our secondary research questions:

o Cerebral perfusion: MRI with Arterial Spin Labeling (pCASL sequence on 3T Philips scanner) will be used measure perfusion levels;

o Vessel diameter as measured with MRA;

o Resting state activity and functional connectivity as measured by BOLD fMRI;

o Structural MRI will be collected using isovoxel T1-weighted data to make volumetric changes during the ECT-course possible.

Study description

Background summary

Rationale: Postictal phenomena, such as sensory, motor or memory deficits, headache, delirium, and psychosis, are common manifestations after epileptic and electroconvulsive therapy (ECT) induced seizures and add to the burden of disease. The pathophysiology of these phenomena is poorly understood and specific treatments are not available. Recently, seizure-induced postictal vasoconstriction with hypoperfusion was observed in experimentally induced seizures in rats. Treatment with acetaminophen or calcium antagonists decreased hypoperfusion and postictal phenomena.

Objective: To study the influence of acetaminophen and nimodipine on postictal phenomena after ECT induced seizures.

Study design: A prospective, three conditions cross-over trial, with randomized condition allocation, open-label, and blinded end-point evaluation (PROBE design).

Study population: Thirty-three adult (age >17 years) patients referred to treatment with ECT for a depressive episode will be included.

Intervention: A single dose of nimodipine (60 mg) or acetaminophen (1000 mg) or no additional treatment will be given prior to each ECT-session. Patients will be randomly assigned to predefined treatment sequences.
Main study parameters/endpoints: The primary outcome measure is the duration of the postictal phase as measured electrographically and expressed as ‘time to EEG normalization’. Secondary outcome measures include clinical ‘time to orientation’ and postictal cerebral perfusion as measured by perfusion weighted MRI.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Acetaminophen (Paracetamol) is a widely used analgesic drug. A single dose of 1000mg has no relevant side effects. Nimodipine in a dose of 60mg, 6 times daily during three weeks, is part of standard treatment for prevention of vasoconstriction in patients with subarachnoid haemorrhage and generally well tolerated. A single dose of 60mg may in a few cases cause a temporary reduction in blood pressure. Since this treatment is administered in the highly-controlled environment of an operation theatre, where ECT takes place, we consider this associated risk as negligible. MRI scanning and cognitive evaluation shortly after the ECT-session may be perceived as inconvenient by some patients, but we foresee no relevant additional risks. Important possible benefits include a reduction of postictal symptoms with acetaminophen or nimodipine treatment in the future.

Study objective

We hypothesize that acetaminophen and nimodipine have a positive influence on postictal phenomena after ECT induced seizures and this is mediated by a reduction of postictal cerebral hypoperfusion.

Study design

Baseline: next to standard structural MRI and EEG, the additional MRI scans will be performed, as well as the psychological inventory.

After each ECT-session: reorientation time (ROT) and VAS-scores of myalgia, headache and nausea.

After three of the ECT-sessions: MRI-scans (see secondary outcomes) within 1 hour of ECT.

End of ECT-course: psychological inventory.

3 months after ECT-course: psychological inventory next to common practice EEG and MRI.

Intervention

A single dose of nimodipine (60 mg) or acetaminophen (1000 mg) or no additional treatment will be given prior to each ECT-session. Patients will be randomly assigned to predefined treatment sequences.

Contacts

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Eligibility criteria

Inclusion criteria

Adulthood (age > 17 years);

Current clinical diagnosis of depressive episode (unipolar, bipolar, schizoaffective);

Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements.

Exclusion criteria

Known adverse reactions to acetaminophen or nimodipine. In that case participants can still be included into the other intervention groups;

Chronic use of acetaminophen, calcium-antagonists or NSAID’s that cannot be interrupted for less than two days before the ECT-session.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2019
Enrollment:	33
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 13-01-2019
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48237
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7476
NTR-old	NTR7718
CCMO	NL68690.091.19
OMON	NL-OMON48237

Study results