Preventing Relapse After Successful Electroconvulsive therapy (ECT) for Depression: A randomized controlled trial on lithium as add-on to personalized maintenance ECT

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Although electroconvulsive therapy (ECT) is an effective treatment for depression, preventing relapse after successful ECT remains a major challenge. In the PRASED-study we evaluate the effectiveness of three strategies to reduce relapse: an...

Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON49873

Source
ToetsingOnline

Brief title
PRASED

Condition

- Mood disorders and disturbances NEC

Synonym
depression, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Antwerpen
Source(s) of monetary or material Support: FWO (Fonds voor wetenschappelijk onderzoek - Vlaanderen)

Intervention

Keyword: depression, ECT, lithium, relapse

Outcome measures

Primary outcome

Improvement of prevention of relapse by 20%

Secondary outcome

n.a.

Study description

Background summary

The combination of antidepressants, personalized M-ECT and lithium has been studied in an elderly population and proved to be very effective, but the efficacy in a severely depressed population of all ages has never been assessed. This project holds great promise for reducing relapse rates after successful ECT, thereby being of potential impact for a vulnerable group of patients with an often recurring and debilitating major depressive disorder. Apart from a significant positive medical impact, reducing relapse rates eventually also has a socio-economic impact by reducing health care costs.

Study objective

Although electroconvulsive therapy (ECT) is an effective treatment for depression, preventing relapse after successful ECT remains a major challenge. In the PRASED-study we evaluate the effectiveness of three strategies to reduce relapse: an algorithm-based symptom-driven form of maintenance-ECT (M-ECT), with antidepressants, with or without lithium.

Study design

In the four treatment centers, patients that are referred for ECT for

depression will be screened for eligibility. In phase 1 240 patients are treated with an acute course of brief pulse ECT, combined with open label nortriptyline or venlafaxine. Patients that achieve remission, are considered eligible for phase 2 of the study. In this continuation phase, open label antidepressants are continued and algorithm-based, symptom-driven M-ECT is started for the next six months. Patients will be randomized to receive either lithium or not. After six months, patients enter phase 3, a naturalistic follow-up of mood at 3 and 6 months after completion of phase 2.

Intervention

In addition to ECT and antidepressants, one of the two participating groups will receive lithium. Other that that, both the procedure and the treatment and all assessments (test material) in the two groups are identical.

Study burden and risks

The Administration of intended test batteries will require some effort from the participants. On the other hand, the patients who have been included in the study so far in Belgium experience assessments of their mood and cognitive functioning as extra attention and care, which motivates them further and compensates for the negative aspects (time).

For further risks, see E9.

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 patients
- Treatment with either an adequately dosed TCA (with therapeutic blood levels) or venlafaxine (target dose of >= 225mg/day)
- Remitted (IDS-C<=12) after an acute course of ECT
- Age 18 or older

Exclusion criteria

- Patients with bipolar disorder, schizoaffective disorder or schizophrenia
- Patients already treated with Lithium, or with a contra-indication for Lithium use
- Patients with documented dementia or intellectual disability
- Substance abuse or dependence in the past 6 months

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-01-2021
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Generic name:	electroconvulsiontherapy (ECT)
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Camcolit
Generic name:	lithiumcarbonaat
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-12-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2019-000135-11-NL

Register	ID
CCMO	NL71540.078.19