Optimization of electroconvulsive therapy (ECT) and continuation pharmacotherapy in major depressive disorder

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Does ECT in combination with nortriptyline result in a more likely and or faster response than ECT alone? Does continuation pharmacotherapy with nortriptyline result in a lower relapse rate or longer time to relapse in responders to ECT in...

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

Summary

ID

NL-OMON33909

Source
ToetsingOnline

Brief title
Optimization of ECT

Condition

- Mood disorders and disturbances NEC

Synonym
depression, Major depression

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Continuation pharmacotherapy, Electroconvulsive therapy, Major depressive disorder, Prevention of relapse

Outcome measures

Primary outcome

Treatment phase I:

· Mean reduction in Hamilton Rating Scale for Depression (HRSD)-score

· Response (reduction HRSD score >= 50%, Clinical Global Impression (CGI) at

least *much improved* compared to baseline)

· Time to response

· Remission (post ECT HRSD score <= 7)

Treatment phase II:

· Relapse (HRSD > 14 and reduction HRSD score < 50%, CGI at least *much worse*

compared to baseline)

· Time to relapse

Secondary outcome

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Study description

Background summary

About 50-60% of depressed inpatients treated with electroconvulsive therapy (ECT) show response in an average of 6-8 weeks. ECT in combination with a tricyclic antidepressant, instead of ECT alone, may enhance the efficacy of ECT

and decrease the time to response.
Despite continuation pharmacotherapy, relapse rate during one year following ECT exceeds 50%. The combination of ECT with a tricyclic antidepressant and continuation of this antidepressant after the course of ECT may decrease relapse rate.
Some depressed inpatients show no suppression on the dexamethasone suppression test, probably as a result of a higher hypothalamic-pituitary-adrenal axis activity resulting in hypercortisolism. This can partly be explained by differences in glucocorticoid sensitivity, which is influenced by polymorphisms in the glucocorticoid receptor gene.

Study objective

Does ECT in combination with nortriptyline result in a more likely and or faster response than ECT alone?
Does continuation pharmacotherapy with nortriptyline result in a lower relapse rate or longer time to relapse in responders to ECT in combination with nortriptyline compared to responders to ECT alone?

Study design

Treatment phase I: double blind placebo controlled study.
Treatment phase II: longitudinal follow-up study.

Intervention

Treatment phase I: one group receives ECT in combination with nortriptyline, the other group ECT in combination with placebo.
Treatment phase II: all participating patients (responders treatment phase I) receive nortriptyline.

Study burden and risks

The burden for participating patients is very low. The greater part of the study is part of the standard procedure in the Erasmus MC and UMC Groningen during hospitalisation and ECT treatment of patients with a depressive disorder. The results can be of clinical relevance; a more likely and faster response to ECT and reduction of relapse rate after successful ECT.

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 (DSM-IV-TR)
Hamilton Rating Scale for Depression >= 18
ECT indication
Age 18-80
If age >= 65 years, first depressive episode before age 65 and Mini Mental State Examination >= 24
At least 5 days free from medication before start doubble blind medication/ECT
Informed consent

Exclusion criteria

Alcohol- or drug dependence last 3 months
Serious neurologic illness
Endocrinologic illness affecting HPA-axis
Use of anti-epileptic medication
Bipolar disorder, schizoaffective disorder, schizophrenia
Contra-indication for nortriptyline

Pregnancy or possibility for pregnancy and no adequate contraceptive measures

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-03-2010
Enrollment:	90
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Aventyl
Generic name:	Nortriptyline
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	25-05-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	27-08-2009
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	EUCTR2008-0044830-2-NL
CCMO	NL23948.078.09