

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Mood disorders and disturbances NEC
<b>Study type</b>	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  $\geq 50\%$ , Clinical Global Impression (CGI) at least \*much improved\* compared to baseline)
- Time to response
- Remission (post ECT HRSD score  $\leq 7$ )

Treatment phase II:

- Relapse (HRSD  $> 14$  and reduction HRSD score  $< 50\%$ , CGI at least \*much worse\* compared to baseline)
- Time to relapse

### Secondary outcome

-

## 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**

### **Public**

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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  $\geq 18$

ECT indication

Age 18-80

If age  $\geq 65$  years, first depressive episode before age 65 and Mini Mental State Examination  $\geq 24$

At least 5 days free from medication before start double 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