Optimization of the antidepressant effect of electroshock

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20033

Source
NTR

Health condition

Major depression; nortriptyline; ECT; combination treatment; tricyclic antidepressants

Dutch keywords: Depressieve stoornis; nortriptyline; ECT; combinatie behandeling; tricyclische antidepressiva

Sponsors and support

Primary sponsor: Erasmus MC Rotterdam
Source(s) of monetary or material Support: Erasmus MC, Lundbeck BV (unrestricted grant).

Intervention

Outcome measures

Primary outcome

Mean change in HAM-D score

Proportion of responders (≥ 50% reduction of HAM-D score)

Proportion of remitters (final HAM-D score 7 or lower)

Secondary outcome

Speed of response defined as the number of ECT sessions required for remission.

Study description

Background summary

ECT is a very effective treament for patients with severe major depression. However, it is unclear whether combining ECT with an antidepressant results in an increased efficacy and/or a faster antidepressant response. Furthermore, relapse following succesfull ECT is a relevant problem. Possibly combining ECT with an antidepressant may prevent some of the early relapse after ECT.

In this double-blind study patients are randomised to either treatment with ECT and nortriptyline or ECT and placebo. At baseline, and weekly thereafter the HAM-D and CGI are assessed, in order to determine response, remission, and the speed of response.

Study objective

Is there a diiference in antidepressant efficacy between ECT and a combination of ECT and nortriptyline?

Does combination therapy with ECT and nortriptyline result in a faster antidepressant response compared with ECT monotherapy?

Does combination therapy result in less relapse after termination of the ECT course, compared with ECT monotherapy?

Study design

HAM-D and CGI at baseline, weekly until the end of the ECT course.METC

Intervention

ECT + nortriptyline versus ECT + Placebo

Contacts

Public
Erasmus MC
E.M. Pluijms
Rotterdam
The Netherlands
+31107033636
Scientific
Erasmus MC
E.M. Pluijms
Rotterdam
The Netherlands
+31107033636

Eligibility criteria

Inclusion criteria

• Diagnosis Major depression according to DSM-IV-TR, established with depression part of the SADS

• Baseline HAM-D score ≥ 18

• Indication for treatment with ECT (insufficient response during 4 weeks treatment with a tricyclic antidepressant with adequateplasmalevel or 4 weeks venlafaxine dosed 225 mg/day or higher)

• Age > = 18
• If age ≥ 65 ,first depressive episode before the age of 65.

• If age ≥ 65, intact cognitive functioning (MMSE 24)

• Informed consent (patient or their legal relatives, in case of in case of incapacity)

Exclusion criteria

• Alcohol or drugdependecy during the last 3 months.

• Severe neurological disorders.

• Endocrinological disorders influencing HPA-axis

• The use of antiepileptics.

• Bipolar disorder, schizoaffective disorder or schizophrenia

• Contraindication for nortriptyline

• Pregnancy or inadequate contraception in fertile women.

• Insufficient mastering of Dutch language..

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	90
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	22-12-2015
Application type:	First submission

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
NTR-new	NL5346
NTR-old	NTR5579
Other	METC Erasmus MC : METC 2009-176

Study results

Summary results
N/A