Optimization of the antidepressant effect of electroshock

Gepubliceerd: 22-12-2015 Laatst bijgewerkt: 13-12-2022

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…

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20033

Bron
NTR

Aandoening

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

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

Ondersteuning

Primaire sponsor: Erasmus MC Rotterdam
Overige ondersteuning: Erasmus MC, Lundbeck BV (unrestricted grant).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

ECT + nortriptyline versus ECT + Placebo

Contactpersonen

Publiek

Erasmus MC

E.M. Pluijms
Rotterdam
The Netherlands
+31107033636

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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..

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2010
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	22-12-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5346
NTR-old	NTR5579
Ander register	METC Erasmus MC : METC 2009-176

Resultaten

Samenvatting resultaten
N/A