

ECT and Memantine.

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

Samenvatting

ID

NL-OMON27602

Bron

NTR

Verkorte titel

ECT and Memantine

Aandoening

Electroconvulsive therapy
Cognitive side effects
Memantine
Electroconvulsieve therapie
Cognitieve bijwerkingen
Memantine
Depression
Depressie

Ondersteuning

Primaire sponsor: Parnassia Psychomedical Center The Hague

Erasmus University Medical Center Rotterdam, dept of Psychiatry

Overige ondersteuning: Initiators. Lundbeck provided verum and placebo study medication

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Scores on a standard cognitive testbattery. This test is administered before, during and after ECT and at follow-up. This testbattery has been proven to be sensitive to cognitive side-effects of depression and also for the ECT effects in depression.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

The efficacy of ECT for the treatment of mood disorders requires the induction of generalized seizures (Nobler et al., 1993). Following the repeated induction of generalized seizures through ECT, enhanced excitability and altered histologic characteristics of the hippocampus have been well demonstrated (Gombos et al., 1999; Perera et al., 2007). Although hippocampal excitotoxicity is mediated in part by excessive calcium influx through over-activation of NMDA receptors, physiological NMDA receptor activation is essential for normal neuronal function. Therefore, potential neuroprotective agents that block virtually all NMDA receptor activity will very likely have unacceptable side effects. In contrast to other clinically-available NMDA receptor antagonists, memantine has been demonstrated to substantially reduce excitotoxic neuronal injury, as well as being clinically well-tolerated in humans. The superior efficacy and clinical safety of memantine result from its highly advantageous pharmacological properties (Chen et al., 1998). Memantine has the unique attributes of being an open-channel blocker, as well as having a relatively fast dissociation rate, compared with other NMDA antagonists such as ketamine. Therefore, memantine will only block NMDA receptors that are excessively stimulated (open-channel blockade) without disrupting normal synaptic transmission (fast dissociation rate). Together, memantine represents a novel, low-affinity, open-channel NMDA antagonist that appears to enter the channel preferentially when pathologically activated without interfering with normal synaptic transmission, yielding the potential to

provide neuroprotection.

Onderzoeksopzet

During the course of ECT treatment and at 2 months follow-up.

Onderzoeksproduct en/of interventie

1. The experimental group will receive once daily 20 mg/d memantine during ECT. This will be titrated before commencing ECT;
2. The control group will receive an identical placebo once daily.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

DSM-IV criteria for unipolar or bipolar depression and a clinical indication for

electroconvulsive
treatment (ECT).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with organic brain syndrome, Mini-Mental State Exam score lower than 24, schizophrenia, schizoaffective disorder, use of lithium or inadequate command of the Dutch language will be excluded.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-12-2012
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	15-12-2012
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	NL3587
NTR-old	NTR3753
CCMO	NL33782.097.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A