Prediction of ECT treatment response and reduction of Cognitive Side-effects using EEG and Rivastigmine

Gepubliceerd: 26-08-2021 Laatst bijgewerkt: 18-08-2022

Rivastigmine will protect against the cognitive and memory side effects of ECT

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

Samenvatting

ID

NL-OMON27806

Bron
NTR

Verkorte titel
PRECISER

Aandoening

Depression

Ondersteuning

Primaire sponsor: UMC Groningen (investigator initiated)
Overige ondersteuning: ZonMw - Goed Gebruik Geneesmiddelen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The first objective is to investigate whether rivastigmine could protect against the cognitive (and memory) side effects of ECT. Cognitive (and memory) side effects will be quantified

using: the Dutch Rey Auditory Verbal learning Test (D-RAVLT, “15 woorden test”), the word fluency test, the Montreal Cognitive Assessment (MoCA) and the Columbia Autobiographical Memory Interview [CUAMI (McElhiney, Moody, & Sackeim, 2001; Mulder, Dekker, & Dekker, 2006; Nasreddine et al., 2005; Van der Elst et al., 2005)].

Toelichting onderzoek

Achtergrond van het onderzoek

Electroconvulsive therapy (ECT) is the most potent psychiatric treatment, with an effect size of 1.5 for severe and refractory unipolar and bipolar depression. ECT convincingly outperforms pharmacotherapy such as tricyclic antidepressants and monoamine oxidase inhibitors and any form of psychotherapy. Despite its outstanding performance in reducing depressive symptoms up to the point of full remission, it is used only frugal. A recent Dutch study calculated that currently only 1.2% of chronic depressive patients are offered ECT, while 26% could actually benefit from this treatment. Unfortunately, the response to ECT is largely unpredictable, while cognitive side-effects occur frequently.
In a previous study, we found that multiple cognitive tests showed a significant decline immediately post-ECT, which resolved within 6 months after the last ECT session. Even though cognitive side-effects are mostly short-lasting, patients and doctors see this as a great drawback of ECT. If these disturbing side-effects could be prevented, more patients and psychiatrists would choose ECT as a treatment option for this severely ill group. This would lead to a more effective treatment and hence shorter duration of chronic severe depression and improvement in quality of life, while costs for health care and loss of productivity would decrease. A potential way of ameliorating side effects, could be to add a cholinesterase inhibitor to ECT treatment. Recent rodent studies show that the loss of cholinergic fibers specifically correlated to the cognitive side effects of rodents after electroconvulsive stimulation (ECS). We select rivastigmine (a cholinesterase inhibitor) as a potential candidate in counteracting cognitive side effects induced by cholinergic fiber loss due to ECT. Rivastigmine patches are very well tolerated and widely used for Alzheimer’s Disease.
Tailoring treatment to patients that are likely to respond while cognitive side-effects are unlikely to occur, would be another important improvement of clinical care for patients with otherwise treatment-resistant depression. Currently, ECT treatment outcome is unpredictable. Factors that favor response include older age, psychotic depression, shorter duration of the depressive episode, rapid response (if patients respond before the 6th session, the chance of remission is higher) and smaller dentate gyrus volumes. However, these predictors are insufficiently accurate to make individual response profiles. Accurately classifying specifically non-responders will prevent application of ineffective treatment with potential iatrogenic damage, while more accurately predicted response will increase the applicability of ECT as treatment option. A potentially powerful way which is easy to implement in the clinic is prediction of ECT treatment response using EEG characteristics in addition to clinical information
The aim of our study is two folded: first, we aim to improve cognition after ECT, improving its acceptability and tolerability and hence increase its application. If ECT would be used for the

calculated 26% of patients who have chronic severe depression, morbidity and mortality of this disorder would decrease steeply. Second, we aim to develop a prediction method based on clinical and EEG characteristics, to accurately predict who will respond to ECT. If it is possible to accurately predict ECT response (and non-response), it could be prevented that patients with a low chance of recovery receives ECT without response but with the associated risks.

Doel van het onderzoek

Rivastigmine will protect against the cognitive and memory side effects of ECT

Onderzoeksopzet

baseline, after first ECT, exit, 3 months follow-up

Onderzoeksproduct en/of interventie

Rivastigmine addition to ECT-course

Contactpersonen

Publiek

University Medical Center Groningen
Jasper Nuninga

0639139525

Wetenschappelijk

University Medical Center Groningen
Jasper Nuninga

0639139525

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age over 18 years
- Clinical indication for ECT (as indicated by the treating physician/psychiatrist)
- A depressive episode (as assessed by the treating psychiatrist)
- Fluent in Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Currently receiving, or having received ECT 6 months prior to the start of the treatment/study.
- Currently using rivastigmine, galantamine, donezepil (or another cholinesterase inhibitor).
- Pregnancy and/or lactation/breast feeding
- Suspicion of neurodegenerative disorders (as diagnosed earlier)
- Contraindications for ECT (recent myocardinfarct, recent cerebrovasculair accident, recent intracranial surgery, pheochromocytoma and instable angina pectoris)
- Contraindications for rivastigmine (bradycardia or atrioventricular (AV) conduction disorders (first degree AV-block excluded))
- Patients who have had an allergic reaction to rivastigmine
- Cognitive disorder not explained by the depressive episode

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	29-09-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	26-08-2021
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	NL9683
Ander register	METC Utrecht : 21-120/G-M

Resultaten