ECT for patients suffering from clozapine resistant schizophrenia

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ECT is effective as treatment of psychosis in patients suffering from clozapine resistant schizophrenia.

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

Samenvatting

ID

NL-OMON21329

Bron
NTR

Verkorte titel
N/A

Aandoening

psychosis, schizophrenia, clozapine, electroconvulsive therapy

Ondersteuning

Primaire sponsor: GGZ Delfland
Overige ondersteuning: GGZ Delfland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Positive symptoms score on the Positive and Negative syndrome scale (PANSS)

Toelichting onderzoek

Achtergrond van het onderzoek

In the Netherlands electroconvulsive therapy (ECT) is mainly used for treatment of depression. The ECT guidelines from the Nederlandse Vereniging van Psychiatrie (NVVP 2000) broaden the use of ECT. These guidelines recommend the use of ECT for treatment of schizophrenia when an adequate treatment with clozapine has not been efficacious. There is however little evidence for the efficacy of ECT in clozapine resistant schizophrenia. In this study the efficacy of ECT in the treatment of schizophrenia is explored in patients who are still suffering from psychosis despite adequate treatment with clozapine. Patients are randomized in two groups. In the control group patients continue treatment with clozapine. In the treatment group patients receive ECT treatment and clozapine is also continued. The primary outcome criterion is the reduction in positive symptoms of schizophrenia, which is assessed using the Positive and Negative Syndrome Scale (PANSS). In the follow up phase the time to relapse after a successful ECT course is explored. A single blind, prospective, randomized, controlled study design is used.

Doel van het onderzoek

ECT is effective as treatment of psychosis in patients suffering from clozapine resistant schizophrenia.

Onderzoeksopzet

Baseline, two weeks, four weeks, six weeks (end point)

Onderzoeksproduct en/of interventie

Clozapine vs. clozapine + ECT

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age: 18 yrs or older

2. Suffering from schizophrenia

3. Able to give informed consent

4. Treatment with clozapine for at least eight weeks with blood levels of at least 350 ng/ml has been shown to be inadequate

5. Inadequate treatment is defined as a score of at least 4 on 2 of the 4 psychotic items (paranoia, delusions, hallucinations, formal thought disorder) of the Brief Psychiatris Rating Scale (BPRS)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Contra-indication for ECT: myocardial infarction less than 3 months old

2. Drugs or alcohol abuse less than a month ago

3. Clozapine blood levels higher than 1000 ng/ml

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	11-02-2003
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-04-2008
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	NL1246

Register	ID
NTR-old	NTR1292
Ander register	: METC/2003-139/ME 03-08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A