Onderzoek naar het effect van de toevoeging van D-cycloserine aan exposure sessies bij de behandeling van patiënten met een obsessieve-compulsieve stoornis.

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

Samenvatting

ID

NL-OMON27916

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Obsessive-compulsive disorder
(NLD: Obsessieve-compulsieve stoornis).

Ondersteuning

Primaire sponsor: Meerkanten GGZ
Ermelo
Overige ondersteuning: Meerkanten GGZ en subsidie van Stichting tot steun VCVGZ.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The differences in scores on the Y-BOCS (clinical interview) between baseline and half-way and afterwards the series of ERP sessions will be taken as the primary outcome measure. The mean scores of the two groups (placebo vs. DCS) at these time points will be compared and analyzed. One and three months after the scheduled ERP sessions, when patients may have received further regular CBT, the Y-BOCS will be done again and it can be determined if acceleration of effect results in better outcome at follow up.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Obsessive-compulsive disorder (OCD) is a disabling disorder with a prevalence of about 1%. Exposure and response prevention (ERP) is an evidence-based treatment for patients with OCD. Extinction of conditioned anxiety is a key element of this treatment method. Althought ERP is effective in OCD, treatment effects are fairly often rather limited or absent. So there is a need for new means and/or methods in order to enhance the effects of ERP. In animal studies it has been shown that extinction of conditioned anxiety is enhanced by acute doses of D-cycloserine (DCS) in combination with exposure. Two clinical studies concerning patients with acrophobia and social anxiety, have shown that addition of DCS to exposure sessions improved treatment results.

Objective of the study:

The aim of this pilot-study is to establish the potential efficacy of acute doses of 50 mgs D-cycloserine (DCS), a partial NMDA agonist, in accelerating and/or augmenting the effect of exposure and response prevention (ERP) in the treatment of obsessive-compulsive disorder (OCD).

Study design:

A randomised, dubble-blind, placebo controlled study design. It is a parallel design with two arms.

Study population:

Patients with OCD according to DSM-IV, with ages of 18 years and older.

Intervention (if applicable):

Both groups will receive a series of 6 (plus one introductioin session) structured exposure and response prevention sessions. One group will take capsules with 125 mgs of DCS prior to each treatment session, the other group will get capsules with placebo.

After this structured treatment phase patients will receive further CGT without addition of DCS/placebo. In this phase further treatment effects will be assessed.

Primary study parameters/outcome of the study:

Improvement of OCD symptoms as measured by the YBOCS during and directly afterwards the structured ERP treatment and 1 month and 3 months later.

Secundary study parameters/outcome of the study (if applicable):

Assessments of the rate of anxiety and avoidance related to specific target symptoms.

Also the CGI and the PADUA-R will be done.
Response percentages (defined as minimal 30% reduction on the Y-BOCS) will be compared.

Doel van het onderzoek

The aim of this pilot-study is to establish the potential efficacy of D-cycloserine (DCS), a partial NMDA agonist, in accelerating and/or augmenting the effect of exposure and response prevention (ERP) in the treatment of obsessive-compulsive disorder (OCD).

Onderzoeksopzet

At baseline, during and directly afterwards the structured ERP treatment and 1 month and 3 months later.

Onderzoeksproduct en/of interventie

Acute doses of 125 mg D-cylcoserine or placebo 1 hour before 6 weekly exposure sessions.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with a primary DSM-IV diagnosis of OCD with an age of 18 years and older as established with the Structural Clinical Interview for axis I DSM-IV Disorders (SCID I);

2. Obsessive-compulsive complaints has to be such that exposure in vivo is feasible at the

outpatient department, in the clinic or the direct environment;

3. Patients have to understand the rationale of exposure therapy and there has to be a readiness to participate in exposure sessions;

4. If a patient uses medication, dosages have to be stable (no changes in the last 2 months and during the study period);

5. Negative pregnancy test (â-HCG in urine).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Addiction to alcohol or drugs or abuse of these compounds;

2. A primary diagnosis of a personality disorder;

3. Psychotic disorder;

4. Relevant somatic disorders;

5. Suicidal intentions;

6. Pregnancy or breastfeeding;

7. Usage of medication possibly interfering with DCS (isoniazide, protonionamide).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2008
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-01-2008
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	NL1146
NTR-old	NTR1189
Ander register	Meerkanten GGZ Ermelo : MK200702
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A