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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27916

Source
NTR

Brief title
N/A

Health condition

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

Sponsors and support

Primary sponsor: Meerkanten GGZ
Ermelo
Source(s) of monetary or material Support: Meerkanten GGZ en subsidie van Stichting tot steun VCVGZ.

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

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

2. CGI and the PADUA-R;

3. Response percentages (defined as minimal 30% reduction on the Y-BOCS) will be compared.

Study description

Background summary

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.

Study objective

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).

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2008
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion Date:	17-01-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1146
NTR-old	NTR1189
Other	Meerkanten GGZ Ermelo : MK200702
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A