The effect of the addition of D-cycloserine to exposure sessions in the treatment of patients with obsessive-compulsive disorder.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON30642

Source
ToetsingOnline

Brief title
DCSOCD

Condition

- Anxiety disorders and symptoms

Synonym
Obsessive-compulsive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Meerkanten GGZ (Ermelo)

Source(s) of monetary or material Support: onderzoekfonds instelling; Stichting Steun (aangevraagd).

Intervention

Keyword: D-cycloserine, Exposure and response prevention, Obsessive-compulsive disorder

Outcome measures

Primary outcome

Improvement of OCD symptoms as measured by the YBOCS during and directly

afterwards the structured ERP treatment and 1 month and 3 months later.

Secondary outcome

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 description

Background summary

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.

Study objective

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.

Intervention

Both groups will receive a series of 6 (plus one introductioin session) structured exposure and response prevention sessions. One group will take capsules with 50 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.

Study burden and risks

De belasting bestaat vooral uit extra tijdsinvestering van de patiënt i.v.m. vragenlijstafnames en 'wachttijd' vanwege het feit dat de capsule DCS/placebo een uur voorafgaand aan de behandelsessies wordt ingenomen.
In de gebruikte dosering is de kans op bijwerkingen minimaal.

The burden for patients consists mainly of extra investments of time for interviews and rating scales, and 'waiting time' when patients receive the capsules one hour before starting the ERP sessions.
With the acute doses used in this study the risks of adverse events are minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 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)
- Obsessive-compulsive complaints has to be such that exposure in vivo is feasible at the outpatient department, in the clinic or the direct environment.
- Patients have to understand the rationale of exposure therapy and there has to be a readiness to participate in exposure sessions.
- If a patient uses medication, dosages have to be stable (no changes in the last 2 months and during the study period).
- Negative pregnancy test (β-HCG in urine).

Exclusion criteria

- Addiction to alcohol or drugs or abuse of these compounds
- A primary diagnosis of a personality disorder
- Psychotic disorder
- Relevant somatic disorders
- Suicidal intentions
- Pregnancy or breastfeeding
- Usage of medication possibly interfering with DCS (isoniazide, protonionamide)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Cycloserine
Generic name:	D-cycloserine

Ethics review

Approved WMO

Date:	08-05-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Approved WMO

Date:	12-07-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen

	Geestelijke Gezondheidszorg (Utrecht)
Approved WMO Date:	09-09-2010
Application type:	Amendment
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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
EudraCT	EUCTR2007-000367-18-NL
CCMO	NL15991.097.07