DCS as an enhancer of ERP in panic disorder and OCD.

Gepubliceerd: 11-10-2009 Laatst bijgewerkt: 18-08-2022

1. DCS enhances the speed and size of effect of exposure therapy in panic disorder and OCD; 2. This DCS enhancement is independent of the nature of the anxiety provoking situations (OCD-related versus panic-related); 3. There is no difference in...

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

Samenvatting

ID

NL-OMON25942

Bron
Nationaal Trial Register

Verkorte titel
DCS study

Aandoening

Panic disorder with agoraphobia, and obsessive-compulsive disorder are studied using DCS either before or afer exposure with response prevention sessions.

Ondersteuning

Primaire sponsor: Utrecht University, department of clinical psychology
Overige ondersteuning: ZONMW, the VEMI program

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

in Panic disorder+agorphobia: the Mobility Inventroy (Chambless, 1985).

In OCD: the YBOCS severity scale (Goodman, 1989).

Toelichting onderzoek

Achtergrond van het onderzoek

Obsessive Compulsive Disorders (OCD) and Panic Disorder + Agoraphobia (PD+AGO) are anxiety disorders that are among the most prevalent disorders in mental health care. Analyses show that the United States economy loses over $42 billion each year as a result of public health costs due to anxiety disorders. Currently, behavior therapy (Exposure and Response Prevention; ERP) is the treatment of choice, either alone or in combination with serotonin reuptake inhibitors. Although ERP has proven to result in significant symptom reduction in about 60% of patients, a significant number of individuals fail to respond to sufficiently to treatment.

Procedurally, exposure is based on extinction of conditioned fear. Recent work in rodents and humans has demonstrated that acute treatment with D-Cycloserine (DCS) a partial agonist of the NMDA-receptor, enhances the learning and memory processes underlying extinction of fear.
It is of great interest to study whether addition of DCS to ERP treatment in patients with anxiety
disorders leads to improvement of treatment effect, speed of ERP effect and/ or, as a consequence, diminished costs. In OCD, the first clinical studies performed so-far strongly suggest that DCS, administered either within 1 hour before or directly after ERP, enhances the effect of ERP in the first 5-6 sessions. In panic disorder –the “model” anxiety disorder-, DCS has barely been investigated, but first results of enhancement with DCS of interoceptive exposure to panic sensations suggest enhanced treatment effect and higher remission rates in patients. This study aims at extending current knowledge about the ERP enhancing effects of DCS in OCD and panic disorder with agoraphobia.

Objectives: The first objective of this study is whether DCS addition to exposure therapy enhances symptom reduction in OCD and PD+AGO. The second objective of the study is to establish the optimal timing of administration of D-Cycloserine (directly pre- or post ERP). The third objective is, to study the fear extinction enhancement of DCS using a neuropsychological paradigm. The fourth objective is, from a health economic perspective, to establish cost-effectiveness of DCS. The hypotheses are that improvement will occur, at a faster rate, with addition of DCS, which will result in less therapy sessions needed and thus cost reduction.

Study design: This double blind placebo controlled trial involves 60 patients with OCD, and 60 patients with PD+Ago, randomized to treatment with either placebo, or single fixed dosages of 125mg DCS in the first 6 sessions of a 12 session program of ERP, either 30 minutes before

or after each weekly 60-90 minute standardized exposure therapy session. Thus, patients with OCD and with PD+AGO will be randomly allocated to 1 of 3 possible conditions. Patients in condition 1 will receive DCS before and placebo after exposure sessions. Patients in condition 2 will receive Placebo both before and after exposure sessions. Patients in condition 3 will receive placebo before and DCS after exposure sessions.

This study is a collaborative project between the department of Psychiatry, AMC (co-applicant prof. Denys) on the one hand, and the Academic Anxiety outpatient clinic of Altrecht Utrecht and the Department of clinical psychology, Utrecht University(Dr. Cath, principal Investigator) on the other. For patient recruitment and inclusion, departments will collaborate with the anxiety outpatient clinic of GGZ InGeest Amsterdam and the anxiety outpatient clinic of Meerkanten, Ermelo.
Treatment effect and effects on fear extinction, learning and habituation are measured after each session, directly post treatment (after 12 ERP sessions) and at 6 months follow-up. Health care use, and costs, quality of life, and loss of work productivity are measured pre, directly post treatment and at follow-up.

Doel van het onderzoek

1. DCS enhances the speed and size of effect of exposure therapy in panic disorder and OCD;

2. This DCS enhancement is independent of the nature of the anxiety provoking situations (OCD-related versus panic-related);

3. There is no difference in effect related to time of administration of DCS (before versus after the end of an ERP session);

4. The mechanism of effect acts through stronger and faster extinction of lower level anxiety processes.

Onderzoeksopzet

At baseline, after 3 and 5 ERP sessions, at post treatment (after 12 ERP sessions), at follow-up fter 6 months and 1 year.

Onderzoeksproduct en/of interventie

Both study groups n=60 (OCD and n=60 panic disorder+ agorphobia patients) receive 12 ERP standard sessions, and in the first 6 sessions they receive study medication either directly pre or post session.

Thus of each study group, n=20 patients receive DCS directly pre and placebo directly post session, n=20 patients receive placebo directly pre and DCS directly postsession, and n=20 patients receive placebo both pre- and post sessions.

Contactpersonen

Publiek

Utrecht university, department of clinical psychology
PO BOx 80140
G. Boois, de
Utrecht university, department of clinical psychology
PO BOx 80140
Utrecht 3508 TC
The Netherlands
-

Wetenschappelijk

Utrecht university, department of clinical psychology
PO BOx 80140
G. Boois, de
Utrecht university, department of clinical psychology
PO BOx 80140
Utrecht 3508 TC
The Netherlands
-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A DSM IV diagnosis of panic disorder with agoraphobia, or obsessive-compulsive disorder.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Mental deficiency;

2. Inability to speak or read Dutch;

3. Severe co-morbid psychiatric diagnoses.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-01-2010
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-10-2009
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	NL1933
NTR-old	NTR2050
Ander register	ZONMW : 17100 1007
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A