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

No registrations found.

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

Summary

ID

NL-OMON25942

Source
Nationaal Trial Register

Brief title
DCS study

Health condition

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

Sponsors and support

Primary sponsor: Utrecht University, department of clinical psychology
Source(s) of monetary or material Support: ZONMW, the VEMI program

Intervention

Outcome measures

Primary outcome

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

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

Secondary outcome

In both patient groups, the following measures will be taken at baseline, mid-treatment,at post-test and FU:

1. Beck Anxiety Inventory (BAI; Beck, 1990), on global anxiety severity;

2. Clinical Global Impression (CGI; Guy, 1976);

3. Hamilton Depression Rating Scale (HDRS; Hamilton, 1960);

4. Hamilton Anxiety Rating Scale (HARS;Hamilton, 1960);

5. Sheehan Disability Scales (SDS; Sheehan, 1998);

6. WHOQOL (Quality of Life; WHOQOL Group, 1996);

7. The Fawcett side effects checklist (Fawcett, 1987);

8. In PD+AGO, the Panic disorder severity scale (Shear, 1997; measures panic symptom severity),the Body Symptoms Questionnaire (BSQ; Chambless,1985; measures physiological panic symptoms, and the Agoraphobic Cognitions Questionnaire (ACQ; Chambless, 1985) is taken at baseline, post-test and FU;

9. In OCD, the Dutch Dimensional Obsessive Compulsive Scale (DDOCS; Denys et al.2005), and the Brown assessment of Belief Scale (BABS; Eisen et al, 1998) are taken at baseline, and at posttest and FU.

31-aug-2014:
For the OCD population, we made no changes in primary outcome measure (Y-BOCS), but we used these secondary outcome measures: CGI, HDRS, HARS, SDS, WHOQOL, TicP and MOS-SF (instead of the original described secondary outcome measures: BAI, CGI, HDRS, HARS, SDS, WHOQOL, Tic-P, Fawcett, DDOCS and BABS).

For the panic disorder population, we made no changes in primary outcome measure (Mobility Inventory), but we used these secondary outcome measures: BAI, PDSS, SUDS, BDI, WHOQOL, Fawcett and Tic-P (instead of the original described secondary outcome measures: BAI,PDSS,SUDS, CGI,HDRS, HARS, SDS, WHOQOL, Tic-P, Fawcett, BSQ and ACQ).

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

1. Mental deficiency;

2. Inability to speak or read Dutch;

3. Severe co-morbid psychiatric diagnoses.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2010
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-10-2009
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	NL1933
NTR-old	NTR2050
Other	ZONMW : 17100 1007
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A