Body Dysmorphic Disorder: Pharmacological enhancement of fear extinction; a randomized placebo controlled, double blind study.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Somatic symptom and related disorders
Study type	Interventional

Summary

ID

NL-OMON33898

Source
ToetsingOnline

Brief title
DCS addition in BDD

Condition

- Somatic symptom and related disorders

Synonym
Body Dysmorphic Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Body Dysmorphic Disorder, D-cycloserine, Exposure and Response Prevention, Fear Extinction

Outcome measures

Primary outcome

The change in BDD-Yale Brown Obsessive Compulsive Scale (BDD-YBocs) and time of

onset of change on the BDD-YBOCS.

Secondary outcome

VLGT : Verbal Learning and Memory Test

WCST: Wisconsin Card Sorting Test

TOL: Tower of London

ET: Extinction Task

CGI: Clinical Global Impression scale

BABS: Brown Assessment of Belief Scale

HDRS: Hamilton Depression Rating Scale

HARS: Hamilton Anxiety Rating Scale

SDS: Sheehan Disability Scales

WHOQOL World Health Organization Quality of Life

Study description

Background summary

Body Dysmorphic Disorder (BDD) is a chronic and severe psychiatric disorder which affects 1-7% of the general population. Cognitive Behavioural Therapy is currently the treatment of choice for BDD and aims to help patients changing

their thoughts and behaviours. High rates of suicide attempts, severe impairment in psychosocial functioning and decreasing daily functioning are very common among BDD patients. Procedurally, CBT is based on altering negative appraisal of body imaging and core beliefs as well as 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. Adding DCS to behavioural exposure therapy might improve treatment outcome in BDD.

Study objective

The objective for this study is threefold. First we will determine whether DCS addition to behavioural exposure therapy may enhance fear extinction and improve symptoms in BDD. Our hypothesis is that improvement will occur and at a faster rate than with no addition of DCS. Furthermore, we will examine the underlying pathophysiologic mechanisms of fear extinction in BDD with neuro-imaging studies. The brain activity of the amygdale and cortico-striatal circuits will be assessed in fifty patients before and after treatment with citalopram and before and after exposure treatment with DCS by means of functional magnetic resonance imaging (fMRI) in a fear extinction paradigm. Finally, we will examine if DCS has an effect on learning, memory and executive tasks. We hypothesize based on rodent and limited human studies that DCS is a performance enhancer in different learning, memory and executive tasks.

Study design

A randomized, double blind, placebo-controlled fixed dose study.

Intervention

Half of the subjects will be randomly assigned to the placebo condition and the other half will be randomly assigned to receive DCS. All subject will receive 24 weeks CBT including exposure therapy. During week 2-8 subjects will receive the assigned study medication 30 minutes prior to exposure therapy.

Study burden and risks

Side-effects of D-Cycloserine are limited, since study dosing is low (50 mg). Exept for this small chance on side effects, there are serious risks associated to this study. Advantages to the subjects can be expected because of the potential therapeutic effect (faster reduction in OCD-symptoms and lower drop-out rates). Futhermore, the results can offer insight into the pathofysiology of OCD and may lead to future development of more effective treatmentmethods.

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

- All patients meet the DSM-IV criteria for BDD
- Male and female, aged between 18-65 years
- Female patients of childbearing potential must have a negative pregnancy test and use reliable method of contraception.
- Written informed consent
- Eligible for exposure therapy
- Right-handed

Exclusion criteria

Presence of any of the following DSM IV conditions:

* Major depression (HDRS * 15)
* Bipolar Disorder
* Schizophrenia or any other psychotic disorder
* Tic disorder
* Substance related disorder during the past 6 months
* Epilepsy or any structural CNS disorder of stroke within the last year;- Presence of primary or co-morbid personality disorder
- Evidence of clinically significant and unstable cardiovascular, gastrointestinal, pulmonary, Renal, hepatic, endocrine or haematological disorders, glaucoma, myocardial infarction within de past year or micturition abnormalities.
- Currently taking benzodiazepines
- Patients at risk for suicide
- Multiple serious drug allergies of known allergy for DCS
- Inability to speak Dutch or English

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):	01-04-2009
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Seromycin

Generic name:	D-cycloserine

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Amsterdam UMC

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	EUCTR2009-010927-26-NL
CCMO	NL24146.018.09