Een gerandomiseerde placebo gecontroleerde studie naar de toegevoegde waarde van D-cycloserine aan exposure therapie bij pati??nten met een poststraumatische stress stoornis

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The present study is aimed at testing the effects of D-cycloserine in addition to exposure treatment sessions in PTSD patients, in a randomized double blind placebo controlled study.

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

Summary

ID

NL-OMON31376

Source
ToetsingOnline

Brief title
D-cycloserine in exposure treatment for PTSD

Condition

- Anxiety disorders and symptoms

Synonym
emotional processing of a traumatic event, flashbacks

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Nijmegen (Nijmegen)
Source(s) of monetary or material Support: Subsidie is aangevraagd bij Achmea Stichting Slachtoffer Fonds en bij

Intervention

Keyword: D-cycloserine, exposure, PTSD, Treatment outcome

Outcome measures

Primary outcome

The primary outcome measure is PTSD symptom severity, measured with a clinician rated instrument (the Clinician-Administered PTSD Scale, CAPS-1; Blake et al., 1995; Dutch translation: Klinisch Interview voor PTSS, KIP; Hovens, Luinge & Van Minnen, 2005; Interview, 28 items).

Secondary outcome

Secondary outcome measures will be general psychopathology measures, f.i. depression and work and social functioning.

Study description

Background summary

After experiencing a traumatic event, such as rape or an armed robbery, people may develop a Post Traumatic Stress Disorder (PTSD). PTSD is classified in the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV; APA, 1994) as an anxiety disorder. Patients suffering from PTSD typically re-experience the traumatic event again and again, as if it was happening here and now, in flashbacks and nightmares. These re-experiences are highly fearful to patients. Therefore they avoid as much as they can to think about the traumatic event, and they avoid situations that may trigger such memories. In addition, because they are afraid that something bad can happen again, they are therefore continuously alert for possible threats, leading to severe sleeping and concentration problems. Exposure-based treatments are thus far the most effective treatment for patients with PTSD. These treatments are based on

emotionally processing the feared stimuli, in which two conditions are necessary: fear activation and cognitive (un)learning. When these two conditions are met, extinction can take place. However, there is a need for improvement of the treatment approach to increase the number of patients who benefit from the treatments, to lower the level of residual symptoms after treatments and to lessen the emotional burden of the treatment. The present study aims at the improvement of exposure therapy -at this moment the most effective psychotherapeutic treatment programme- by augmentation with D-cycloserine, a newly discovered drug for enhancing learning processes such as extinction.
The augmentation of D-cycloserine to exposure therapy is a promising approach to improve treatment results of exposure-based treatments in patients with anxiety disorders.

Study objective

The present study is aimed at testing the effects of D-cycloserine in addition to exposure treatment sessions in PTSD patients, in a randomized double blind placebo controlled study.

Study design

The proposed study is a randomized and placebo double blind controlled trial. After inclusion, patients are randomized in two treatment conditions; (1) exposure plus D-Cycloserine and (2) exposure plus placebo. Both groups receive an effective therapy program for PTSD, exposure therapy. Both groups will receive 8-12 sessions of imaginal exposure at the outpatient clinic. An hour before the imaginal exposure sessions, the experimental group will use D-cycloserine 50 mg. The control group will use a placebo an hour before the exposure sessions.

Intervention

The exposure treatment is manualized and consists of 8-12 weekly sessions. In the first session patients are educated about PTSD symptoms and about the treatment rationale. In the next sessions, patients are instructed to recount aloud the traumatic event in the first person and in the present tense with closed eyes. They are further instructed to imagine the traumatic event as vividly as possible, as if the trauma is happening *here and now*. They are asked to recount the traumatic memory and to focus on details of the event, as well as their emotions, and thoughts. Throughout the imaginal exposure, anxiety levels are monitored each 5 minutes using the SUDS (Subjective Units of Distress Scale, range 0-10). Each exposure session is recorded and as *homework*, patients are asked to listen to the recording five times a week at home. In addition to this homework audiotape listening, patients are given in-vivo exposure assignments. The in-vivo assignments are initiated after the

second imaginal exposure session, and include real life exposure to fearful stimuli related to the trauma, such as visiting the trauma place or watching a movie related to the trauma.
Note that the exposure treatment is the most effective treatment for PTSD patients and is the treatment *as usual*. In addition, the exposure treatment will be identical for both treatment groups. Groups only differ in the drug they take before the exposure sessions at the clinic.

Study burden and risks

Given the limited time burden on patients, and the safety of the used drugs, in our opinion, this study should be classified as a low or negligible risk study.

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

Inclusion criteria are (1) age between 18 and 65 and (2) current DSM-IV diagnosis of PTSD established with a structured diagnostic interview (M.I.N.I. and CAPS).

Exclusion criteria

Diagnostic exclusion criteria are (1) psychosis or delusion disorders (current or in the past) (2) suicidality (3) mental retardation (4) substance abuse or dependence or alcohol abuse of dependence, as established by a structured diagnostic interview (M.I.N.I.). Medical exclusion criteria are (1) pregnant or lactating women. Also women who are planning a pregnancy and don???t want to postpone a pregnancy during the treatment phase are excluded. According to the Informatorium Medicamentorum (2006), the influence of the use of D-cycloserine during pregnancy and breastfeeding is unknown. However, for safety reasons, we exclude these women. (2) patients who have a serious and unstable medical illness, as confirmed by their doctor, such as use of a pacemaker, renal disease or porfyrie (3) a history of epileptic seizures (4) medication use that may interfere with D-cycloserine, such as anticoagulants (5) patients who use antidepressants

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	niet bekend
Generic name:	D-cycloserine

Ethics review

Approved WMO Date:	27-11-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25674
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2007-003891-20-NL
CCMO	NL17389.091.07
OMON	NL-OMON25674