Augmentation of (imaginal) exposure therapy with D-cycloserine for patients with Posttraumatic Stress Disorder (PTSD); A Randomized Placebo controlled Study.

No registrations found.

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

Summary

ID

NL-OMON25674

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Posttraumatic Stress Disorder
(NLD: Posttraumatische stress stoornis).

Sponsors and support

Primary sponsor: GGz Nijmegen
Source(s) of monetary or material Support: Stichting Achmea Slachtoffer en Samenleving

Intervention

Outcome measures

Primary outcome

PTSD symptoms.

Secondary outcome

1. Depression;

2. anxiety;

3. Posttraumatic Cognitions;

4. avoidance behavior.

Study description

Background summary

The present study aims at the improvement of exposure therapy for PTSD patients–at this moment the most effective psychotherapeutic treatment programme- by augmentation with D-cycloserine, a newly discovered drug for enhancing learning processes.

Study objective

D-cycloserine will improve the effects of exposure therapy.

Study design

Pre and posttreatment and follow-ups after 3, 12 en 24 months.

Intervention

Exposure therapy with D-cycloserine or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

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

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.);

5. 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;

6. patients who have a serious and unstable medical illness, as confirmed by their doctor, such as use of a pacemaker, renal disease or porfyrie;

7. a history of epileptic seizures;

8. medication use that may interfere with D-cycloserine, such as anticoagulants;

9. patients who use antidepressants, and are not willing to stop;

10. Patients who use benzodiazepines are included only when they completely stop taking benzodiazepines before the start of the treatment;

11. insufficient ability to speak and write Dutch.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2008
Enrollment:	102
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-12-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 31376

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1142
NTR-old	NTR1184
CCMO	NL17389.091.07
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON31376

Study results

Summary results
N/A