Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Efficacy of D-Cycloserine for Treatment of Numbing and Avoidance in patients with Chronic PTSD

Protocol summary

Summary

Aims: The aim of this trial was to investigate the efficacy and tolerability of DCS in treatment of numbing and avoidance in chronic PTSD. Setting and Design: This was an 11-week, double-blind, randomized, placebo-controlled, cross-over clinical trial conducted in out-patient psychiatry clinics affiliated to Isfahan University of Medical Sciences (IUMS). Methods and Material: Inclusion criteria included:Male; age 16-65 years; Being Registered as outpatient chronic combat-related PTSD (based on DSM-IV-TR)in outpatient psychaitry clinicsaffiliated to Isfahan University of Medical Sciences (IUMS). were screened for eligibility (n=319). Exclusion criteria included: comorbid psychiatric condition; comorbid severe medical condition; abnormal physical examination or paraclinical test results. 319 patients were screened. The study sample included 76 subjects who were randomly assigned to two groups (n=38). Patients entered a one-week run-in period. Then, the groups received either an add-on treatment of DCS (50 mg daily), or placebo (4 weeks). After a two-week washout, the groups received cross-over treatments (4 weeks). Clinical interview, Clinician Administered PTSD Scale (CAPS), and clinical/paraclinical assessments were performed at baseline, and at the end of the 1st, 5th, 7th and 11th weeks. Side effects were also evaluatedthrough patient reported side effect questionnaire.

General information

Acronym

D-Cycloserine for Numbing and Avoidance in Chronic PTSD

IRCT registration information

IRCT registration number: **IRCT2013121015741N1**
Registration date: **2013-12-25, 1392/10/04**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-12-25, 1392/10/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

partially supported by Isfahan University of Medical Sciences, Deputy of Research

Expected recruitment start date

2012-10-01, 1391/07/10

Expected recruitment end date

2013-07-01, 1392/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of D-Cycloserine for Treatment of Numbing and Avoidance in patients with Chronic PTSD

Public title

D-cycloserine for numbing and avoidance in chronic PTSD

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion: male; age over 18 and less than 65 years; being registered were registered with chronic combat-related PTSD in University affiliated psychiatric outpatient clinics in Isfahan;if already on psychopharmacologic treatments were required to be on a stable adequate drug regimen for the past three months. Exclusion: criteria of another DSM-IV-TR diagnosis; comorbid psychiatric condition including depression or substance abuse; a comorbid serious medical problem.
Age
From **18 years** old to **65 years** old
Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Etics committee of IUMS, Deputy of Reasearch
Street address
Isfahan University of Medical Sciences, Hezar jerib Ave.
City
Isfahan
Postal code
Approval date
2010-05-20, 1389/02/30
Ethics committee reference number
32454

Health conditions studied

1

Description of health condition studied
Post-traumatic stress disorder
ICD-10 code
F43.1
ICD-10 code description
Post-traumatic stress disorder

Primary outcomes

1

Description
numbing and avoidance scores
Timepoint
1st week, 5th, 7th, 11th weeks
Method of measurement
Clinician Administered PTSD Scale, Criterion C

Secondary outcomes

1

Description
Drug side effects
Timepoint
1st, 5th, 7th,11th weeks
Method of measurement
Drug side effect questionnaire

Intervention groups

1

Description
Capsule D-cycloserine 25 mg twice daily for 4 weeks
Category
Treatment - Drugs

2

Description
placebo twice daily for 4 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
outpatient pschiatry clinics affiliated to Isfahan Univarsity of Medical Sciences
Full name of responsible person
Dr Fatemeh Rajabi, Dr Abbas Attari
Street address
Noor, alzahra, Farabi, Modarres, Amiralmomenin Hospital clinics
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isafahan Univaersity of Medical Sciences, Deputy of Research
Full name of responsible person
Dr Peiman Adibi
Street address
Deputy of Research, Isfahan University of Medical Sciences, Hezarjerib Ave
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isafahan Univaersity of Medical Sciences, Deputy of Research
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty