

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 outpatient 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 psychiatry clinics affiliated 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 evaluated through 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

Name

Fatemeh Rajabi

Name of organization / entity

Isfahan University of medical sciences, Behavioral sciences research center

Country

Iran (Islamic Republic of)

Phone

+98 31 1773 5517

Email address

fara860@yahoo.com

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 University 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

Contact**Name of organization / entity**

IUMS, Behavioral Sciences Research Center

Full name of responsible person

Fatemeh Rajabi

Position

Dr, Resident of Psychiatry

Other areas of specialty/work**Street address**

Noor Hospital, Ostandari Ave.

City

Isfahan

Postal code**Phone**

+98 31 1773 5517

Fax**Email**

fara860@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Behaviral Sciences Research Center, Isfahan University of Medical Sciences

Full name of responsible person

Fatemeh Rajabi

Position

Dr, Resident of psychiatry

Other areas of specialty/work**Street address**

Noor hospital, Ostandari Ave.

City

Isfahan

Postal code**Phone**

+98 31 1773 5517

Fax**Email**

fara860@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Isfahan University of Medical Sciences, Behavioral Sciences Research Center

Full name of responsible person

Fatemeh Rajabi

Position

Dr, Resident of psychiatry

Other areas of specialty/work**Street address**

Noor Hospital, Ostandari Ave.

City

Isfahan

Postal code**Phone**

+98 31 1773 5517

Fax**Email**

fara860@yahoo.com

Web page address

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