

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The efficacy of augment of D-Cycloserine and cognitive-behavioral therapy on symptoms improvement in the adolescents with one type of anxiety disorders: A double-blind randomized controlled trial

Protocol summary

Summary

This study was designed to investigate the effect of combining D-cycloserine (DCS) and cognitive-behavioral therapy (CBT) on the adolescents with at least one type of anxiety disorders. The present study was conducted as a double-blind randomized controlled trial on thirty six adolescents with anxiety disorders in an eight-month period (from September, 2011 to May, 2012) who were assessed in two groups. In this study both patients and the information collectors were unaware about the groups' type. The adolescents with the age of 12- to 20-years and anxiety disorders needing therapeutic interventions and receiving anti-anxiety treatment according to the children psychiatrist, with the Lack of any background pertaining to serious psychological or physical problems, mood disorders, psychosis or delusional disorders and drug dependency, without any changes in taking anti-anxiety drugs or any changes in their doses during the last four weeks, the patients with no learning disorders based on the mental check-up, with the absence of background associated with seizure and severe depression with the suicide thoughts and the IQ equal or higher than 80 (it was measured applying Raven Test and by an independent psychiatrist approval) are included in the study. If the patients were absent for more than one session or their parents or themselves did not intend to continue the treatment they were excluded. Patients were selected in a simple non-random manner and in the order of referring to the clinic and were randomly divided into two eighteen-members groups of case and control by the random-maker software "Random Allocation". In addition to four CBT sessions weekly in both groups. Cases received 50-mg DCS capsules and controls received placebo daily for a month, patients received DCS capsules or placebo one hour before CBT sessions. Age, sex, kind of anxiety disorders "SCARED" and "CATS" scores were evaluated

and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012071610297N1**

Registration date: **2013-08-21, 1392/05/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-21, 1392/05/30

Registrant information

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Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, School of Medicine, Vice Chancellor for Research

Expected recruitment start date

2011-09-01, 1390/06/10

Expected recruitment end date

2012-04-30, 1391/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of augment of D-Cycloserine and cognitive-behavioral therapy on symptoms improvement in the adolescents with one type of anxiety disorders: A double-blind randomized controlled trial

Public title

The efficacy of D-Cycloserine and psychotherapy on symptoms improvement in the adults with anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- The adolescents with the age of 12-20 years with anxiety disorders needing therapeutic interventions and receiving anti-anxiety treatment according to the children psychiatrist, 2- Lack of any background pertaining to serious psychological or physical problems, mood disorders, psychosis or delusional disorders and drug dependency, 3- Lack of any changes in anti-anxiety drugs or any changes in their doses during 4 weeks before the study, 4- Lack of learning disorders based on mental check-up, 5- lack of any background associated with seizure and severe depression coupled with the thoughts of suicide, 6- The IQ equal or higher than 80 (it was measured applying Raven Test and by an independent psychiatrist) are of inclusion criteria. Exclusion Criteria: 1-The patients who were absent for more than one session and those whose parents or themselves did not intend to continue the treatment.

Age

From **12 years** old to **20 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences, Ethics Committee

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq.

City

Isfahan

Postal code**Approval date**

2011-04-20, 1390/01/31

Ethics committee reference number

390609

Health conditions studied**1****Description of health condition studied**

Anxiety Disorders

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

Improvement of the anxiety disorders symptoms

Timepoint

One month after the beginning of the medication and psychotherapy

Method of measurement

"SCARED" score

Secondary outcomes**1****Description**

Children's Automatic Thoughts Scale Score

Timepoint

Three months post treatment

Method of measurement

CATS questionnaire

Intervention groups**1****Description**

Case group received a 50-mg D-cycloserine capsule (made in pharmacology school of Isfahan University of Medical Sciences) daily for a month in addition to the

psychotherapy.

Category

Treatment - Drugs

2

Description

Control group, received Placebo (made in pharmacology school of Isfahan University of Medical Sciences) daily for a month in addition to the sychotherapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Child and Adolescent Psychiatry

Full name of responsible person

Dr. Ali Soheilimehr

Street address

No.3, Nikoo Building, Shamsabadi Ave., Isfahan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, School of Medicine, Vice Chancellor for Research

Full name of responsible person

Dr. Taleb Azarm

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Isfahan University of Medical Sciences, School of Medicine, Vice Chancellor for Research

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of Medical Sciences, School of Medicine, Vice Chancellor for 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

Department of Psychiatry, Isfahan University of Medical Sciences

Full name of responsible person

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Position

Psychiatrist

Other areas of specialty/work

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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*