

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The efficacy of Venlafaxine in comparison with placebo in the treatment of adult with attention deficit hyperactivity disorder: A double blind randomized clinical trial

Protocol summary

Summary

The propose is to study the efficacy of Venlafaxine in the treatment of adult attention-deficit hyperactivity disorder (ADHD). Forty subjects between 18-45 years who clearly meet diagnostic criteria for adult ADHD, from parents and siblings of children with ADHD who are referred to child and adolescent psychiatric clinic of RAZI hospital will assign. Inclusion criteria: confirm of symptoms of ADHD in childhood & diagnosis of ADHD on clinical psychiatric interview. Exclusion criteria: any other psychiatric disorder and physical illness. This is a double blind randomized clinical trial study. Subjects receive either Venlafaxine or placebo randomly for 6 week. Venlafaxine will titrate up during the trial according to the following Schedule: week 1, 2; 75mg/day (once daily), week 3, 4 150mg/day (twice daily) and week 5, 6; 225mg/day (thrice daily). Patients will assess at baseline, 14, 28 and 42 days after the medication start with Adult Conner's questionnaires for assessing severity of symptoms of ADHD. Side effects will systematically record throughout the study and will assess using a checklist that comprises side effects by psychiatrist on days 14, 28 and 42.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808122660N1**
Registration date: **2010-01-25, 1388/11/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-01-25, 1388/11/05

Registrant information

Name

Shahrokh Amiri Aziza Abad

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1380 4486

Email address

amirish@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-21, 1389/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Venlafaxine in comparison with placebo in the treatment of adult with attention deficit hyperactivity disorder: A double blind randomized clinical trial

Public title

Use of Venlafaxine in the treatment of adult attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Age between 18-45 year 2. Having Adult attention deficit hyperactivity disorder (ADHD) according to the judgment of two psychiatrists 3. Confirm of ADHD symptoms at childhood period. Exclusion criteria: 1. Evidence of mental retardation (IQ<70 based on clinical judgment) 2. Other psychiatric comorbidity 3. Any significant chronic medical condition, including organic brain disorder and seizure 4. Current abuse or dependence on substance within 6 months 5. Pregnant and lactating women . 6. use any psychiatric drugs in recent two weeks

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Vice Chancellor for research of Tabriz University of Medical Sciences

Street address

Gol-Gasht

City

Tabriz

Postal code

Approval date

2008-11-16, 1387/08/26

Ethics committee reference number

5/4/7306

Health conditions studied

1

Description of health condition studied

Adult ADHD (Attention-deficit hyperactivity disorder)

ICD-10 code

F90.9

ICD-10 code description

Hyperkinetic disorders

Primary outcomes

1

Description

Improvement in Attention-deficit symptoms

Timepoint

weeks 2, 4 and 6

Method of measurement

According to the self-report Conner's questionnaire

2

Description

Improvement in impulsivity

Timepoint

weeks 2, 4 and 6

Method of measurement

According to the Self-report Conner's questionnaire

3

Description

Improvement in hyperactivity symptoms

Timepoint

weeks 2, 4 and 6

Method of measurement

According to the Self-report Conner's questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Venlafaxine; weeks 1, 2; 75mg/day (once daily), weeks 3, 4 150mg/day (twice daily) and weeks 5, 6; 225mg/day (thrice daily)

Category

Treatment - Drugs

2

Description

Control group: placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatric Hospital
Full name of responsible person
Dr. Shahrokh Amiri , MD
Street address
El-Goli Baulevard
City
Tabriz

Email
Amirish@tbzmed.ac.ir , Sh_Amiri1348@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University Of Medical Sciences
Full name of responsible person
Shahrokh Amiri Azizabad
Position
Child & Adolescent psychiatrist
Other areas of specialty/work
Street address
Razi Psychiatric Hospital, El Goli Boulevard
City
Tabriz
Postal code
Phone
+98 411380448690
Fax
+98 41 1380 3351
Email
Sh_Amiri@tbzmed.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Eteraf Oskouei
Street address
Golgasht
City
Tabriz
Grant name
بودجه پژوهشی
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for Research of Tabriz University of Medical Sciences
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
Tabriz University Of Medical Sciences
Full name of responsible person
Shahrokh Amiri Azizabad
Position
Assistant Professor Of Psychiatry
Other areas of specialty/work
Street address
Razi psychiatric Hospital, El Goli Boulevard
City
Tabriz
Postal code
Phone
+98 411380448690
Fax
+98 41 1380 3351

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University Of Medical Sciences
Full name of responsible person
Soleiman Mohammadzadeh
Position
Psychiatry Residency
Other areas of specialty/work
Street address
Razi Psychiatric Hospital, El Goli Boulevard
City
Tabriz
Postal code
Phone
Fax
Email
seyiwan@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