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 psychiatirc 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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Tabriz Univercity 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 Univercity 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
Asisstant 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

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

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
seiywan@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