

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Venlafaxine versus Citalopram in treatment of acute phase of major depression disorder

Protocol summary

Summary

this double-blind randomized clinical trial is performed on adults who are referred to the psychiatry outpatient clinics of Shahid Sadughi University of Medical Science. A convenience sample of 50 patients of both genders aged 18-54 years is entered in this study. Participants are included in this study if they fulfill the criteria of major depressive disorder according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR), and we use the 17-item Hamilton Depression Rating Scale (HDRS). Patients with other mental illnesses, such as severe major depression, bipolar disorder or anxiety-, alcoholic or drug abuse patients, patients with other significant medical diseases, psychotic patients, pregnant women and breastfeeding mothers, and patients who had been treated with any antidepressants within 4 weeks before the study are excluded. The patients should be medically stable. Using simple randomization, patients who meet all criteria for enrollment are randomly allocated into 2 treatment groups. Both patients and psychiatrist are blinded to the type of treatment. Citalopram is commenced with the initial dose of 10 mg daily, and gradually increases to 40 mg daily. Venlafaxine ER starting dose is 37.5 mg daily, then gradually increases to 150 mg a day. Follow-up visits are every 2 weeks for 8 weeks. We ask patients about any possible side effects, and calculated a HDRS total score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203048513N1**

Registration date: **2014-07-09, 1393/04/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-09, 1393/04/18

Registrant information

Name

Fariba Amini

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

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f_amani_1974@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadughi University of Medical Science

Expected recruitment start date

2012-04-09, 1391/01/21

Expected recruitment end date

2012-09-11, 1391/06/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Venlafaxine versus Citalopram in treatment of acute phase of major depression disorder

Public title

Venlafaxine versus Citalopram in treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria :mild to moderate major depressive disorder ; patients with primary depression or with any symptom in a month ago exclusion criteria : severe depression ;bipolarity ; anxiety disorder ; alcoholic or drug abuse ; patients with other significant medical diseases ; psychotic disorder ; pregnant women and breast feeding mothers

Age

From **18 years** old to **54 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **53**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahid Sadughi University of Medical Science

Street address

Safaieh , Yazd

City

Taft

Postal code

8991683416

Approval date

2012-02-06, 1390/11/17

Ethics committee reference number

142163

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

Major depressive disorder

ICD-10 code

F32.0 ,F32

ICD-10 code description

Mild depressive episode , Moderate depressive episode

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

level of recovery of depression

Timepoint

before of study & follow up visits every a 2-weeksfor 8 weeks.

Method of measurement

checking of hamilton score

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

side effect of drugs

Timepoint

every 2 weeks for 8 weeks

Method of measurement

with history taking & blood pressure checking

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

average 25 patients are randomized in this group.citalopram is commenced with the initial dose of 10 mg daily, and gradually increases to 40 mg daily.this study lasts 8 weeks and we collect patients information including Hamilton Depression scale every a 2 weeks.on each follow up visits ,we ask patients about possible adverse effects and complete its questionnaires.

Category

Treatment - Drugs

2**Description**

average 25 patients are randomized in this group.venlafaxine starting dose is 37.5 mg daily , then gradually increases to 150 mg daily.this study lasts 8 weeks and we collect patients information including Hamilton Depression scale every a 2 weeks.on each follow up visits ,we ask patients about possible adverse effects and complete its questionnaires.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

psychiatry outpatient clinics of yazd university

Full name of responsible person

Dr.fariba amini

Street address

taft.psychiatry hospital

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Sadughi University of Medical Science
Full name of responsible person
Research Assistant
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Safaieh , Yazd
City
Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadughi University of Medical Science

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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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