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 allocate 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.f0llow up visits is every a 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

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Fariba Amini
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
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Iran (Islamic Republic of)
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f_amini_1974@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadughi University of Medical Scieence

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 Medicai Siense

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
cheking 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 cheking

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 very 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 very 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

taft

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadughi University of Medical Science

Full name of responsible person

Research Assistant

Street address

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

Contact

Name of organization / entity

Shahid Sadughi University of Medical Science

Full name of responsible person

Dr.fariba amini

Position

residente of psychiatry

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Shahid Sadughi University of Medical Science

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Dr.fateme hosseini

Position

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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