

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of effect of Venlafaxin and Bupropion in treatment of Depressive episode of Bipolar II disorder

Protocol summary

Study aim

Due to the fact that research on the treatment of bipolar II disorder has not been conducted in our country. The aim of this study was to evaluate and compare the effect of bupropion and venlafaxine in the treatment of bipolar II disorder, which has also been confirmed by new psychiatric authorities.

Design

Clinical trial with control group, with two parallel groups of three-way blind, randomized, phase 2-3 on 60 patients. The Balanced Block method was used for randomization

Settings and conduct

The patient with depressive episode of bipolar II disorder referred to the specialized clinic of Golestan Hospital are randomly divided into two groups and treated with two different drugs. Only the supervisor is aware of the content of the drugs.

Participants/Inclusion and exclusion criteria

Admission Requirement: Participants must meet the DSM V Diagnostic Criteria for Bipolar II Depressive episode. Condition of non-entry: Rapid cycling disorder and mixed episode.

Intervention groups

One group will receive venlafaxine 75 mg daily for 4 weeks and the second group 75 mg bupropion daily for 4 weeks.

Main outcome variables

Treatment of Depressive Episode Bipolar II Disorder.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200913048698N1**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

Registrant information

Name

Khatereh Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

dr.kh.asadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-10, 1399/09/20

Expected recruitment end date

2021-01-09, 1399/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of Venlafaxin and Bupropion in treatment of Depressive episode of Bipolar II disorder

Public title

Comparison of Venlafaxine and Bupropion on depression of Bipolar II disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Depressive episode of Bipolar II disorder according to DSM V Ability to take oral medication informed consent from the patient or parents The patient has not used another antidepressant within four weeks of starting the drug

Exclusion criteria:

Suicidal thought Psychosis The current episode is mixed Rapid cycling Dyspepsia or peptic ulcer Pregnant and lactating women Intellectual disabilities History of alcohol and substance abuse up to six months before the start of the project The patient's depression is caused by a physical illness using drugs or medication Existence of any severe and chronic physical illness, cerebrovascular disease, seizures or history of substance use Psychotic depression

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyst
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used. A computer algorithm written in SAS (Statistical Analysis System) is used for performing a block randomization with randomly selected block size of 4, 8 and 12. Example output from the SAS algorithm; Block 1; size; 4 1. 4. Control 2. 4 Control 3. 4 Intervention 4. 4. Intervention Block 2; size ;4 1. 4 Control 2. 4. Intervention 3. 4 Control 4. 4. Intervention Block 3; size ;8 1. 8. Control 2. 8. Intervention 3. 8. Control 4. 8. Intervention 5. 8. Intervention 6. 8 Intervention 7. 8 Control 8. 8. Control The main idea of block randomization is to divide patients into M blocks of size 2N, so that in each block N patients are assigned to control group and N patients are assigned to intervention group. The selection of blocks is based on individual characteristics. The block is then randomly selected. This method ensures equal treatment allocation per block provided the block is fully utilized. The size of the block, depending on the number of treatments, should be short enough to prevent imbalance, and large enough to prevent guessing treatment allocation in each group during the study. The size of the block should be at least twice the number of treatment groups. The size of the block is not stated in the study so that researchers are blind to it. If the blocks are expressed, the treatment series in each block can be guessed. This can lead to selection bias. The solution to prevent this error is to: (1) Lack of disclosure the block mechanism (2) Use random block size. In each group, the drugs will be given to the

patients in the same way, and the drug will be found on the same days and in the same way. Everyone on the research team, like patients and their families, will be unaware of the treatment groups designed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients are treated with medication packages pre-determined by the study supervisor (supervisor). Drug packages are quite similar in shape. The patient and the facilitator are not aware of the contents of the packages. In addition, collecting patient assessment information and completing forms is done by the project manager and his assistant who are not aware of the content of the packages. The data analysis stage will be performed by the project consultant and the project manager who are not aware of the contents of the drug packages and only the group of patients (group one or two) will be identified for data analysis, so the study is three-blind. And from the stage of patient admission to the study, data collection and data analysis of the contents of the two drug groups is not clear.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Golestan hospital., Golestan alley

City

Ahvaz

Province

Khuzestan

Postal code

61357-33118

Approval date

2020-02-09, 1398/11/20

Ethics committee reference number

IR.AJUMS.REC.1398.831

Health conditions studied

1

Description of health condition studied

Bipolar II disorder

ICD-10 code

F31.81

ICD-10 code description

Bipolar II disorder

Primary outcomes

1

Description

Depression Score Hamilton Questionnaire

Timepoint

Depression score of Hamilton questionnaire is calculated before intervention, and 14, 21 and 28 days after intervention

Method of measurement

Hamilton Questionnaire

Secondary outcomes

1

Description

Hypo mania score with MDQ questionnaire

Timepoint

Before starting the intervention

Method of measurement

MDQ Questionnaire

Intervention groups

1

Description

Intervention group: This group receives 75 mg Bupropion tablets made in Iran equivalent to 75 mg every morning and re-evaluated by Hamilton Depression Inventory two weeks, three weeks and four weeks after the start of the intervention.

Category

Treatment - Drugs

2

Description

Control group: This group receive Venlafaxine 75 mg tablet made in Iran, has been standardized with bupropion, equivalent to 75 mg daily, and after two weeks, three weeks and four weeks from the start of the intervention by the Hamilton questionnaire is re-evaluated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Ahmad Fakhri

Street address

Golestan alley

City

Ahvaz

Province

Khuzestan

Postal code

61357-33118

Phone

+98 61 3374 3038

Fax

+98 61 3374 3038

Email

fakhri_s@ajums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Amir Ahmad Moghaddam

Street address

Golestan Alley

City

Ahwaz

Province

Khuzestan

Postal code

61357-33118

Phone

+98 61 3374 3001

Fax

+98 61 3374 3038

Email

Info@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Khatere Asadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Golestan Alley

City

Ahwaz

Province

Khouzestan

Postal code

61357-33118

Phone

+98 61 3374 3038

Fax

+98 61 3374 3038

Email

dr.kh.asadi@gmail.com

Web page address**Position**

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Psychiatry group office., Golestan hospital., Ahwaz city

City

Ahwaz

Province

Khouzestan

Postal code

61357-33118

Phone

+98 61 3374 3001

Fax

+98 61 3374 3038

Email

dr.kh.asadi@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahwaz University of Medical Sciences

Full name of responsible person

Hamze Rostami

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Golestan Alley

City

Ahwaz

Province

Khouzestan

Postal code

61357-33118

Phone

+98 61 3374 3038

Fax

+98 61 3374 3038

Email

Rostami@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ahwaz University of Medical Sciences

Full name of responsible person

Khatereh Asadi

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific centers are allowed to request documents for scientific use

From where data/document is obtainable

Hamze Rostami; Rostami-h@ajums.ac.ir; 0098 3112848; Ahmad fakhri; fakhri_a@ajums.ac.ir; Khatere Asadi; dr.kh.asadi@gmail.com; Golestan hospital; Ahwaz; Fax:0098 6133743038

What processes are involved for a request to access data/document

Researchers working in academic and scientific centers should send a request for documents to the above address, the files will be sent as soon as possible

Comments