# 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**

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**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:**

Sucidal tought Psychosis The current episode is mixed Rapid cycling Dyspepsia or peptic ulcer Pregnant and lactating women Intellectual disabilitie 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 analyser
- 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 randomaly selected block size of 4, 8 and 12. Example out put 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 eachblock 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 disclose 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**

Khouzestan

**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**
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## Sponsors / Funding sources

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**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

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## 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**