# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Jun 2026

## Comparative study of Bupropion and Citalopram in response rate for patients with Major Depressive Disorder

## Protocol summary

**Study aim**
Comparison of the therapeutic response rate of bupropion and citalopram in outpatient patients with major depressive disorder

**Design**
Patients are randomly placed in one of the two groups treated with bupropion or citalopram. To evaluate the therapeutic response rate, Hamilton Depression Rating Scale (HAM-D) and the cognitive triangle (CTI) questionnaire are used and in three times (before treatment, two weeks after treatment and four weeks after treatment), patients in both groups are placed under these two Tests.

**Settings and conduct**
Eligible patients referred to psychiatric clinic of 5 Azar Gorgan Educational Center are randomly assigned to one of the bupropion or citalopram groups by a psychiatrist and then referred to a psychiatric resident for evaluation based on CTI and HAM-D. Assessments will be done 3 times by the psychiatric resident.

**Participants/Inclusion and exclusion criteria**
criteria of inclusion: diagnosis of major depressive disorder based on structured clinical interview and DSM-5; not taking BZDs, antipsychotics and mood stabilizers, and concurrent psychotherapy, not having medical diseases including cardiovascular disease

**Intervention groups**
Intervention group A receiving bupropion and intervention group B receiving citalopram.

**Main outcome variables**
Objective therapeutic response is based on a decrease of more than 50% of the baseline score on the Hamilton Depression Rating Scale (HAM-D) measured by the assessor. Subjective treatment response is based on a decrease in the score from the baseline score on the TCI self-report questionnaire.

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20190706044121N1**
Registration date: **2020-01-10, 1398/10/20**
Registration timing: **prospective**

Last update: **2020-01-10, 1398/10/20**
Update count: **0**

**Registration date**
2020-01-10, 1398/10/20

**Registrant information**
**Name**
Mitra Joodi Mashad
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2020-01-11, 1398/10/21
**Expected recruitment end date**
2020-06-20, 1399/03/31
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**

Comparative study of Bupropion and Citalopram in response rate for patients with Major Depressive Disorder

**Public title**
Comparative study of Bupropion and Citalopram in response rate for patients with Major Depressive Disorder

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Diagnosis of major depressive disorder based on structured clinical interview and DSM-5 Older than 30 years old Sufficient fluency in Farsi and literacy reading and writing lack of any comorbid disorder, especially anxiety disorders and substance use retarded or normal psychomotor

**Exclusion criteria:**
previous appropriate response to a certain antidepressants taking antidepressants when visiting using BZDs, mood stablizers or antipsychotics concurrent psychotherapy medical conditions including cardiovascular disease suicidal ideations and psychotic symptoms need to admit to the mental ward agitation or mixed mood symptoms

**Age**
From **30 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **104**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Participants in the study were randomly assigned into two groups of intervention (A) and (B). In this way, the cases will be randomly assigned to one of two study groups with the help of random number table and receive the intervention of the same group.

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Golestan University of Medical Sciences

**Street address**
Central organization of Golestan University of Medical Sciences, Hirkan Drive

**City**
Gorgan

**Province**
Golestan

**Postal code**
4918936316

**Approval date**
2019-09-08, 1398/06/17

**Ethics committee reference number**
IR.GOUMS.REC.1398.180

## Health conditions studied

### 1

**Description of health condition studied**
Major Depressive Disorder

**ICD-10 code**
F32

**ICD-10 code description**
Major depressive disorder, single episode

## Primary outcomes

### 1

**Description**
objective treatment response

**Timepoint**
at baseline and 2 and 4 weeks after pharmacotherapy

**Method of measurement**
Reduction of more than 50% of base score on Hamilton Depression Rating Scale (HAM-D)

### 2

**Description**
subjective treatment response

**Timepoint**
at baseline and after 2 and 4 weeks of pharmacotherapy

**Method of measurement**
reduction of baseline score in Cognitive Triad Inventory (TCI)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Bupropion (Welban company) with the starter dose of 75 mg/day and maximum dose of 300 mg daily for at least 4 weeks

**Category**
Treatment - Drugs

**2**

**Description**
Control group: Citalopram Pharmaceutical company Abidi The starting dose of 20 mg daily and a maximum dose of 40 mg daily for at least 4 weeks
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
5 Azar Medical Center
**Full name of responsible person**
Dr Mitra Joodi Mashhad
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Gorgan University of Medical Sciences
**Full name of responsible person**
Mohammad Reza Honarvar
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Health Technology Development Center, the second floor, Library building, Golestan University of Medical Sciences, philosophical complex, 5th km of Sari-Gorgan
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**Web page address**
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Gorgan 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**
Gorgan University of Medical Sciences
**Full name of responsible person**
Dr Mitra Joodi Mashhad
**Position**
Assistant professor
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## Person responsible for updating data

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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**
Only part of the data that is listed in the variables table will be shared without name and in general results.
**When the data will become available and for how long**
Start of access period 6 months after printing results
**To whom data/document is available**
Only for researchers working in academic and academic institutions
**Under which criteria data/document could be used**
For use in meta-analysis and systematic review articles
**From where data/document is obtainable**
Dr mitra Joodi psychiatry department, 5 th Azar hospital, 5 th Azar Ave, Gorgan drmitrajioodi@goums.ac.ir
**What processes are involved for a request to access data/document**
After receiving the request by email or postal address, the researcher will check the request for 10 working days and if the item is usable in professional cases, the data will be provided to the applicant.
**Comments**