Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

+98 17 3234 4198

Email address

drmitrajioodi@goums.ac.ir

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
Street address
Psychiatry Department, 5 th Azar Hospital, 5 Azar Ave
City
Gorgan
Province
Golestan
Postal code
4917761551
Phone
+98 17 3222 0561
Email
drmitrajioodi@goums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Mohammad Reza Honarvar
Street address
Health Technology Development Center, the second floor, Library building, Golestan University of Medical Sciences, philosophical complex, 5th km of Sari-Gorgan
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3242 4377
Email
Roshd.center@goums.ac.ir
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
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address
Psychiatry Department, 5 th Azar Hospital, 5 th Azar Ave
City
Gorgan
Province
Golestan
Postal code
4917761551
Phone
+98 17 3222 0561
Email
drmitrajioodi@goums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr Mitra Joodi Mashhad
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address
Psychiatry Department, 5 th Azar Hospital, 5 th Azar Ave
City
Gorgan

Province
Golestan
Postal code
4917761551
Phone
+98 17 3222 0561
Email
drmitrajioodi@goums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr Rajab Hadadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Psychiatry Department, 5 th Azar hospital, 5 th Azar Ave
City
Gorgan
Province
Golestan
Postal code
4917761551
Phone
+98 17 3222 0561
Email
h_aazh@yahoo.com

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