

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of adding clonidine versus placebo to the standard treatment in patients with bipolar disorder during manic episode: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of adding clonidine versus placebo to the standard treatment in patients with bipolar disorder during manic episode

Design

This is a double-blind randomized clinical trial, phase II, in which 66 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with bipolar disorder during manic episode who will refer to Sina Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years Bipolar disorder during manic episode Need hospitalization Young score of 20 or higher Exclusion criteria: Pregnancy or breastfeeding Sensitivity to lithium or alpha-2 adrenergic receptor stimulants History of suicide, homicide, or suicidal intention History of drug abuse History of using anticholinergic or antidepressant three-cyclic drugs

Intervention groups

Intervention group: Standard treatment plus tablet clonidine 0.2 mg one to three times a day (depending on the severity of the disease) for 24 days Control group: Standard treatment plus placebo one to three times a day (depending on the severity of the disease) for 24 days

Main outcome variables

Primary outcome: Assessing sleep quality Assessing the cognitive status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N295**

Registration date: **2019-09-14, 1398/06/23**

Registration timing: **prospective**

Last update: **2019-09-14, 1398/06/23**

Update count: **0**

Registration date

2019-09-14, 1398/06/23

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of adding clonidine versus placebo to the standard treatment in patients with bipolar disorder during manic episode: a double-blind randomized clinical trial

Public title

Effect of adding clonidine versus placebo to the standard treatment in patients with bipolar disorder during manic episode

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 65 years Bipolar disorder during manic episode Need hospitalization Young score of 20 or higher

Exclusion criteria:

Pregnancy or breastfeeding Sensitivity to lithium or alpha-2 adrenergic receptor stimulants History of suicide, homicide, or suicidal intention History of drug abuse History of using anticholinergic or antidepressant three-cyclic drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-07-20, 1398/04/29

Ethics committee reference number

IR.UMSHA.REC.1398.352

Health conditions studied**1****Description of health condition studied**

Bipolar disorder during manic episode

ICD-10 code

F31.0

ICD-10 code description

Bipolar disorder, current episode hypomanic

Primary outcomes**1****Description**

Assessing sleep quality

Timepoint

Before the intervention and 12 and 24 days after the intervention

Method of measurement

By using Pittsburg Sleep Quality Index (PSQI)

2**Description**

Assessing the cognitive status

Timepoint

Before the intervention and 12 and 24 days after the intervention

Method of measurement

By using Montreal Cognitive Assessment (MOCA) and

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Standard treatment plus tablet clonidine 0.2 mg one to three times a day (depending on the severity of the disease) for 24 days

Category

Treatment - Drugs

2

Description

Control group: Standard treatment plus placebo one to three times a day (depending on the severity of the disease) for 24 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan City

Full name of responsible person

Dr Rana Pezeshki

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3827 4184

Email

r.pezeshki89@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Rana Pezeshki

Position

Resident of Psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3827 4184

Email

r.pezeshki89@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Amir Keshavarzi

Position

Psychiatrist
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Sina Hospital, Mirzadeh Eshghi Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3827 4184
Email
drkeshavarzi@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Jalal Poorolajal
Position
Professor of Epidemiology
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available