Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the therapeutic effect of allopurinol versus placebo on clinical signs and symptoms in patients with manic bipolar disorder: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To compare the therapeutic effect of allopurinol versus placebo on clinical symptoms in patients with manic bipolar disorder. Design: A double blind randomized clinical trial. Setting and conduct: The eligible patients with manic bipolar disorder who will refer to Baharan Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 45 years; manic bipolar disorder; Score of YMRS equal to or greater than28. Exclusion criteria: Pregnancy; breastfeeding; sensitivity to allopurinol; mental disability; diabetes; hypertension; hypothyroiditis; hyperthyroiditis; convulsion; liver failure; renal failure. Intervention group: Routine treatment plus allopurinol 300 mg twice a day orally for 4 weeks. Control group: Routine treatment plus placebo capsule (including cellulose) twice a day orally for 4 weeks. Primary outcome: Severity of clinical signs and symptoms using YMRS questionnaire before intervention and one, two, three, and four weeks after intervention. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710089014N193**
Registration date: **2017-10-17, 1396/07/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Zahedan University of Medical Sciences

Expected recruitment start date

2007-10-23, 1386/08/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of allopurinol versus placebo on clinical signs and symptoms in patients with manic bipolar disorder: a double blind randomized clinical trial

Public title

Comparison of the therapeutic effect of allopurinol versus placebo on clinical signs and symptoms in patients with manic bipolar disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 45 years; manic bipolar disorder; Score of YMRS equal to or greater than28. Exclusion criteria: Pregnancy; breastfeeding; sensitivity to allopurinol; mental disability; diabetes; hypertension; hypothyroiditis; hyperthyroiditis; convulsion; liver failure; renal failure.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

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Vice-chancellor for Research and Technology, Zahedan University of Medical Sciences, Dr Hesabi Square

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Approval date

2017-09-24, 1396/07/02

Ethics committee reference number

IR.ZAUMS.REC.1396.150

Health conditions studied

1

Description of health condition studied

Manic bipolar disorder

ICD-10 code

F30

ICD-10 code description

Manic episode

Primary outcomes

1

Description

Severity of clinical signs and symptoms

Timepoint

Before intervention and one, two, three, and four weeks after intervention

Method of measurement

Using YMRS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus allopurinol 300 mg twice a day orally for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: Routine treatment plus placebo capsule (including cellulose) twice a day orally for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharan Hospital

Full name of responsible person

Mozhdeh Rigi

Street address

Baharan Hospital, Imam Khomeini Ave.

City

Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research and Technology, Zahedan University of Medical Sciences
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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
Vice-chancellor for Research and Technology, Zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty