Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effectiveness of adding celecoxib to sodium valproate in the treatment of patients with bipolar disorder

Protocol summary

Study aim
Investigating the effect of celecoxib on bipolar disorder
Design
A controlled, parallel-group, double-blind, randomized clinical trial on 60 patients. Randomization using Permuted block randomization method.
Settings and conduct
Patients referred to the clinics and inpatient department of Shahid Yaheinejad Hospital of Babol, whose diagnosis is bipolar disorder. 30 of the participating patients will receive celecoxib and 30 of the patients will receive placebo. The patients will be evaluated by the young mania questionnaire. In the present study, except for the statistical analyst, the rest of the presenters are blind.
Participants/Inclusion and exclusion criteria
Inclusion criteria: having a bipolar disorder and over 18 years of age. Exclusion criteria: dementia, drug use except for cigarettes and caffeine, serious cardiovascular and kidney diseases.
Intervention groups
Intervention group: receives celecoxib. Control group: receives placebo.
Main outcome variables
Treatment of signs and symptoms in patients diagnosed with bipolar disorder.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221216056832N1**
Registration date: **2023-02-01, 1401/11/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-01, 1401/11/12**
Update count: **0**
Registration date
2023-02-01, 1401/11/12

Registrant information
Name
Farzan Kheirkhah
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 4253 9727
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-12-31, 1401/10/10
Expected recruitment end date
2024-02-29, 1402/12/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of adding celecoxib to sodium valproate in the treatment of patients with bipolar disorder

Public title
Investigating the effect of celecoxib on the treatment of bipolar disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having bipolar disorder Age above 18 years
Exclusion criteria:

History of dementia Existence of serious cardiovascular and kidney disease Consumption of substances except for smoking and caffeine

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using permutation blocks. In this method, the size of the blocks will be 4 and the ratio of two groups in each block will be 1:1. In each block, there will be an equal number of each group, i.e. (2 valproate + placebo) and (2 valproate + celecoxib). In each block, the arrangement of two groups is in random order and this random order was determined by a statistician. In order to hide the treatment process, random codes are written on the medicine canisters, and when drugs are allocated, the codes are recorded on the patients' files. The opening of the codes will be done by a statistician after the study is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to hide the treatment process, random codes are written on the medicine cans, and when drugs are allocated, the codes are recorded on the patients' files. In case of side effects, the codes are opened. Otherwise, the codes will be opened and analyzed at the end of the study. The use of placebo medicine will be used in a completely similar way in terms of shape and color in the same package. A placebo (oral capsule containing 1000 mg of lactose) is made.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Mazandaran-Babol- Shahid Yaheinejad Hospital

City

Babol

Province

Mazandaran

Postal code

4717641367

Approval date

2022-12-12, 1401/09/21

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.190

Health conditions studied

1

Description of health condition studied

Bipolar Disorder

ICD-10 code

F31.2

ICD-10 code description

Bipolar disorder, current episode manic severe with psychotic features

Primary outcomes

1

Description

Bipolar affective disorde

Timepoint

2, 4 and 8 weeks after starting celecoxib

Method of measurement

Young mania questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: including 30 people in the group treated with celecoxib 400mg along with sodium valproate 20mg/kg daily for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: 30 children will be treated with placebo (oral capsule containing 1000 mg lactose) and sodium valproate 20 mg/kg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Patients referring to the clinics and inpatient department of Shahid Yaheinejad Hospital

Full name of responsible person
Farzan Kheirkhah

Street address
Babol - Shahid Yahainejad Hospital

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4717641367

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr. Mehdi Rajab Nia

Street address
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drfarzankh@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Farzan Kheirkhah

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

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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