

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Celecoxib added to mood stabilizer for treating acute mania: A randomized, double-blind, placebo-controlled trial

#### Protocol summary

Registration timing: **prospective**

#### Study aim

The efficacy of celecoxib in the treatment of mania

Last update: **2020-03-28, 1399/01/09**

Update count: **0**

#### Design

Clinical trial with control group, parallel groups, double blind, randomized, phase 3, 120 patients

#### Registration date

2020-03-28, 1399/01/09

#### Settings and conduct

Patients who agree to participate in group therapy are randomly divided into two groups of intervention and control groups. Patients in the intervention group receive sodium valproate (mood stabilizer) and 400 mg / day celecoxib in two divided doses. The control group is also prescribe sodium valproate and placebo with the same form and taste as celecoxib in two divided doses daily. Each group is followed for 4 weeks to improve the symptoms of mania base on the Mania Young Rating Scale. This evaluation is perform at week 0, 2, and 4 by an evaluator who is blind to the intervention.

#### Registrant information

##### Name

najmeh shahini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3215 5653

##### Email address

drshahini.n@goums.ac.ir

#### Participants/Inclusion and exclusion criteria

1- Age between 18 and 65 years. 2. Diagnosis according to DSM-1V criteria by a psychiatrist. 4. Fill out the informed consent form. 5. Absence of other axis disorders 6. No other supportive therapy or use of cognitive therapy.

#### Recruitment status

**Not yet recruiting**

#### Funding source

#### Intervention groups

Patients in the intervention group receive sodium valproate and 400 mg twice daily. The control group is also prescribe sodium valproate and placebo with the same form and taste as celecoxib in two divided doses daily.

#### Expected recruitment start date

2633-12-15, 2012/09/24

#### Expected recruitment end date

2641-04-19, 2020/01/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Main outcome variables

mania

#### Scientific title

Celecoxib added to mood stabilizer for treating acute mania: A randomized, double-blind, placebo-controlled trial

#### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200306046708N1**

Registration date: **2020-03-28, 1399/01/09**

#### Public title

Evaluation of the efficacy of celecoxib in the treatment of acute mania

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Eligible for Mania Course based on DSM IV - TR Diagnostic Criteria No other supportive therapy or use of cognitive therapy. Age between 18 and 65 years. Fill out the informed consent form.

### Exclusion criteria:

Causing side effects. Willingness to exit the study  
Unavailability of the patient.

## Age

From **20 days** old to **60 days** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The randomization method is in a simple way. The randomization tool is random numbers table, with even numbers for one group and odd numbers for another. Hiding random allocation using envelopes sealed

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants; Principal Investigator both are blind to allocation to groups. But the analyzer and the other researcher are aware of type of medications in each group.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical Committee of Mashhad University of Medical sciences

##### Street address

Hore Ameli

##### City

Mashhad

##### Province

Razavi Khorasan

## Postal code

0098

## Approval date

2015-04-21, 1394/02/01

## Ethics committee reference number

921878 Mashhad University Of Medical Science

## Health conditions studied

### 1

#### Description of health condition studied

mania

#### ICD-10 code

F31.1

#### ICD-10 code description

Bipolar disorder, current episode manic without psychotic features

## Primary outcomes

### 1

#### Description

mania

#### Timepoint

baseline, 4, 8, 12 weeks

#### Method of measurement

young questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Valproate plus celecoxib 400 mg daily (200 mg twice daily)

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Valproate plus placebo is given twice daily

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ibn e Sina Hospital

##### Full name of responsible person

Najmeh Shahini

##### Street address

Ibn-e-Sina Hospital, Bu-Ali Sq., Amel Blvd.,

Mashhad,Iran.

**City**

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**Province**

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**Postal code**

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**Phone**

+98 17 3215 5653

**Email**

najmeh.shahini@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mahyar Mirheydari

**Street address**

Vice Chancellor For Research Of Mashhad University  
Of Medical Sciences

**City**

Mashhad

**Province**

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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**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Najmeh Shahini

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Ibn-e-Sina Hospital, Bu-Ali Sq., Amel Blvd.,  
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**City**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Najmeh Shahini

**Position**

Associate Profesor

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

Bachelor

**Other areas of specialty/work**

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

journal

**When the data will become available and for how long**

Two years after completion

**To whom data/document is available**

all

**Under which criteria data/document could be used**

all

**From where data/document is obtainable**

email

**What processes are involved for a request to access data/document**

Then print

**Comments**