

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim

The efficacy of celecoxib in the treatment of mania

Design

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

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.

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.

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.

Main outcome variables

mania

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200306046708N1**

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

Registration timing: **prospective**

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

Update count: **0**

Registration date

2020-03-28, 1399/01/09

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

Recruitment status

Not yet recruiting

Funding source

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

Scientific title

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

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

Mashhad

Province

Razavi Khorasan

Postal code

0098

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

Razavi Khorasan

Postal code

0098

Phone

+98 17 3215 5653

Email

najmeh.shahini@gmail.com

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.,
Mashhad,Iran.

City

Mashhad

Province

Razavi Khorasan

Postal code

0098

Phone

+98 17 3215 5653

Email

najmeh.shahini@gmail.com

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

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

0098

Phone

0098172155653

Email

najmeh.shahini@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Najmeh Shahini

Position

Associate Professor

Latest degree

Bachelor

Other areas of specialty/work

Psychiatrics

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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