

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of celecoxib as an adjunct in the treatment of bipolar disorder: A double blind and placebo controlled trial

Protocol summary

Summary

The aim of the present study is to assess the efficacy of Celecoxib as an adjuvant agent in the treatment of bipolar disorder (mania episode) in a six-week double-blind, placebo controlled trial. 50 patients with mania hospitalized in Roozbeh and Qods Hospitals who meet inclusion criteria will participate in the trial. Patients will be randomly allocated into two groups. The first group (25 patients) will receive Valproate 600-800 mg/day plus Celecoxib 400 mg/day (200 mg bid); the second group (25 patients) will receive Valproate 600-800 mg/day plus placebo. Severity of mania and extrapyramidal side effects will be assessed by Young Mania Rating Scale and Extrapyramidal Symptoms Rating Scale (ESRS) at baseline and after 1, 2, 4 and 6 weeks after the trial started. Liver function tests will be done 4 weeks after the medication started.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307171556N53**

Registration date: **2013-07-18, 1392/04/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-07-18, 1392/04/27

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences; Kurdistan University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of celecoxib as an adjunct in the treatment of bipolar disorder: A double blind and placebo controlled trial

Public title

Efficacy of celecoxib in the treatment of bipolar disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: meeting the DSM-IV criteria for Bipolar Disorder; age between 18 and 65 years; a score of at least 20 points on the Young Mania Rating Scale; Exclusion criteria: hyper- or hypothyroidism; substance dependence (except for Nicotine); IQ lower than 70; history of allergy to Celecoxib; lactating and pregnant women; gastro-intestinal ulcer or hemorrhage; cerebrovascular hemorrhage; severe hepatic disease

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshvarz Blvd

City

Tehran

Postal code

Approval date

2013-07-13, 1392/04/22

Ethics committee reference number

22216

Health conditions studied

1

Description of health condition studied

Bipolar Disorder

ICD-10 code

F31

ICD-10 code description

Mania episode

Primary outcomes

1

Description

Severity of mania

Timepoint

Baseline and weeks 1, 2, 4, 6

Method of measurement

by Young Mania Rating Scale

Secondary outcomes

1

Description

Severity of extrapyramidal side effects

Timepoint

Baseline and weeks 1, 2, 4, 6

Method of measurement

By Extrapyramidal Symptom Rating Scale(ESRS)

Intervention groups

1

Description

Intervention group: Valproate 600-800 mg/day plus

Celecoxib 400 mg/day for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: Valproate 600-800 mg/day plus placebo for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

South Kargar Sreet, Roozbeh Hospital

City

Tehran

2

Recruitment center

Name of recruitment center

Qods Hospital

Full name of responsible person

Dr. Farzin Rezaei

Street address

Qods hospital, Pasdaran Blvd., Sanandaj

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Akbar Fotouhi

Street address

Keshvarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice chancellor for research, Kurdistan University of Medical Sciences

Full name of responsible person

Dr Ataollah Heydari

Street address

Pasdaran Blvd, Kurdistan university of Medical Sciences, Deputy of research, Sanandaj Sanandaj

City

Sanandaj

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, Kurdistan University of Medical Sciences

Proportion provided by this source

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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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