

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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**

Rozeb Hospital

**Full name of responsible person**

Dr. Shahin Akhondzadeh

**Street address**

South Kargar Sreet, Rozeb 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****Street address**

South Kargar street; Roozbeh Hospital

**City**

Tehran

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+98 21 5541 2222

**Fax****Email**

s.akhond@sina.tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

Prof. of Clinical Psychopharmacology

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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*