

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation and comparison of the effects of celecoxib and placebo on the brain-derived neurotrophic factor and on the severity of mania in patients with bipolar mood disorder in manic phase undergoing electroconvulsive therapy

Protocol summary

Summary

This study aims to assess the effect of adding celecoxib or placebo to the treatment of manic patients undergoing electroconvulsive therapy (ECT) on the serum level of brain-derived neurotrophic factor and severity of mania. This is a randomized double blind study which is conducted in Tehran. Patients, with the diagnosis of manic episode bipolar mood disorder based on DSM-IV, who are planned to receive ECT are included after obtaining a consent form from the guardians. Patients receive celecoxib (200 mg BD) or placebo a day before beginning of the ECTs and the drug or placebo continues until the end of the 6th ECT session. Blood samples are obtained before the initiation of intervention and are repeated thereafter. Assessment of severity of the disease is done by Young Mania Rating Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401177202N7**
Registration date: **2014-05-10, 1393/02/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-10, 1393/02/20

Registrant information

Name

Padideh Ghaeli

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Faculty of Pharmacy,
Tehran University of Medical Sciences

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effects of celecoxib and placebo on the brain-derived neurotrophic factor and on the severity of mania in patients with bipolar mood disorder in manic phase undergoing electroconvulsive therapy

Public title

Effects of adding celecoxib on brain-derived neurotrophic factor and on the severity of symptoms in patients with bipolar disorder who receive Electroconvulsive therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: meeting the DSM-IV criteria for manic

episode of bipolar mood disorder; age between 17 and 65 years; order of receiving electroconvulsive therapy
Exclusion criteria: history of allergy to NSAIDs; lactating and pregnant women, cerebrovascular hemorrhage; severe hepatic or renal disease, Patients with rheumatologic disease, organic brain syndrome, concomitant taking of other NSAIDs or corticosteroids, severe medical conditions like cardiovascular disorders, respiratory and gastrointestinal disease, receiving electroconvulsive therapy in the past 2 months, stroke, presence of contraindication of receiving electroconvulsive therapy

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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, Tehran University of Medical Sciences

City

Tehran

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

10809-15866

Health conditions studied**1****Description of health condition studied**

Bipolar Mood Disorder, Manic Episode

ICD-10 code

F30

ICD-10 code description

Manic episode

Primary outcomes**1****Description**

changes in brain-derived neurotrophic factor

Timepoint

baseline and after sessions 1,3,6 of ECT

Method of measurement

measurment of serum level

Secondary outcomes**1****Description**

Severity of mania

Timepoint

baseline and after ECT 3 and 6

Method of measurement

by Young Mania Rating Scale

Intervention groups**1****Description**

Intervention group: celecoxib 200 mg BID a day before initiation of the electroconvulsive therapy until the 6th electroconvulsive treatment

Category

Treatment - Drugs

2**Description**

Control group: placebo with similar order as the intervention group and with the same duration

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Roozbeh Hospital

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotouhi

Street address

6th floor, Tehran University of Medical Sciences,
Ghods junction, 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

100

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**

Faculty of Pharmacy, Tehran University of Medical Sciences

Full name of responsible person

Dr Padideh Ghaeli

Position

Professor of Clinical Pharmacy, Faculty of Pharmacy,
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Moan Kargar

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Clinical Pharmacist

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0

Fax**Email****Web page address**

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