

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effects of Celecoxib with placebo on inflammatory factors and cognitive impairment in mood disorder patients undergoing electroconvulsive therapy (ECT)

Protocol summary

Summary

This double-blind randomized clinical trial includes 50 patients with diagnosis of mood disorder according to DSM-IV-TR criteria by a psychiatrist who are candidates to receive electroconvulsive therapy. Before beginning of the first electroconvulsive therapy, every patient undergoes a complete evaluation in terms of biochemical laboratory test and also inflammatory factors and cognition and memory by MMSE, WMS and Stroop. YMRS and Hamilton are used for the evaluation of severity of mood disorder. Patients receive celecoxib 200 mg BID in one group and placebo in the other group. Electrodes in electroconvulsive therapy are placed bilaterally. Patients undergo the same tests during the course of therapy in different time points. The samples for measurement of inflammatory markers IL-1, IL-6, CRP and TNF- α are centrifuged and plasma will be kept at -70 °C frozen. The statistical analysis will be done using SPSS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201247202N2**
Registration date: **2012-02-11, 1390/11/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-11, 1390/11/22

Registrant information

Name

Padideh Ghaeli

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-03-04, 1389/12/13

Expected recruitment end date

2012-03-04, 1390/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Celecoxib with placebo on inflammatory factors and cognitive impairment in mood disorder patients undergoing electroconvulsive therapy (ECT)

Public title

evaluation of adding celecoxib to treatment of mood disorder patients receiving electroconvulsive therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: diagnosis of mood disorder according to DSM IV TR criteria by a psychiatrist. Exclusion Criteria: Patients with Hypersensitivity to celecoxib or other NSAIDs, Patients with rheumatologic disease, Organic Brain Syndrome, Severe Medical Conditions

(cardiovascular disorders, hepatic, renal, respiratory, gastrointestinal), diabetes, patients undergoing treatment with of other NSAIDs or corticosteroids, receiving ECT in the past 2 months, hearing or talking problem and pregnant patients were excluded.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

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 Pharmaceutical Sciences
Research Center of Tehran University of Medical
Sciences

Street address

Faculty of Pharmacy- Tehran University of Medical
Sciences-16th Azar Street- Tehran

City

tehran

Postal code

Approval date

2012-01-28, 1390/11/08

Ethics committee reference number

89-02-33-10809-44959

Health conditions studied

1

Description of health condition studied

mood disorder

ICD-10 code

F30-F39

ICD-10 code description

bipolar affective disorder/ depressive disorder

Primary outcomes

1

Description

change in inflammatory factors

Timepoint

baseline, after ECT 1,3,6

Method of measurement

serum sample

2

Description

change in cognition and memory

Timepoint

baseline, after ECT 1,3,6,

Method of measurement

MMSE,WMS and Stroop

Secondary outcomes

1

Description

efficacy

Timepoint

baseline. after ECT 1,3,6

Method of measurement

Hamilton, YMRS

Intervention groups

1

Description

celecoxib 200 mg BID from a day before first ECT

Category

Treatment - Drugs

2

Description

placebo with the same order and number as celecoxib

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouzbah Hospita of IPsychiatry

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

Vice-Chancellor for Research of Faculty of Pharmacy

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Faculty of Pharmacy-Tehran University of Medical Sciences-16th Azar Street-Tehran

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 of Tehran University of Medical Sciences

Full name of responsible person

Dr Padideh Ghaeli

Position

Associate Professor of Clinical Pharmacy, Faculty of Pharmacy of Tehran University of Medical Science

Other areas of specialty/work

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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