

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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- $\alpha$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 4709

##### Email address

pghaeli@sina.tums.ac.ir

##### 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 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**

Rouzbeh 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 Reseach of Faculty of Pharmacy

**Street address**

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

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## Person responsible for scientific

## inquiries

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Dr Padideh Ghaeli

**Position**

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## Person responsible for updating data

**Contact****Name of organization / entity****Full name of responsible person**

Mona Kargar

**Position**

Pharm D. Resident of clinical pharmacy

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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*