Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A clinical trial of adjunctive Celecoxib treatment in patients with major depression: a double-blind, placebo controlled trial.

Protocol summary

Summary
The purpose of the present investigation is to assess the efficacy of Celecoxib as an adjuvant agent in the treatment of major depression in a six-week double-blind, placebo controlled trial. 40 adult outpatients who meet the DSM- IV-TR criteria for major depression will participate in the trial. Patients who have a baseline Hamilton Rating Scale for Depression score of at least 18 will be allocated into two groups. 20 will receive Fluoxetine 40 mg/day plus Celecoxib 400 mg/day (200 mg bid) (morning and evening) and 20 will receive Fluoxetine 40 mg/day plus placebo. Patients were assessed by a psychiatrist at baseline and after 2, 4 and 6 weeks after the medication started.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT138711141556N5**
Registration date: **2009-03-13, 1387/12/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2009-03-13, 1387/12/23

Registrant information
Name
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Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2007-04-20, 1386/01/31
Expected recruitment end date
2009-04-20, 1388/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A clinical trial of adjunctive Celecoxib treatment in patients with major depression: a double-blind, placebo controlled trial.

Public title
Celecoxib and depression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Presence of Major Depressive Disorder based on DSM-IV criteria, Baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 18.
Exclusion criteria: Presence of Psychosis, any diagnosis in Axis I and II, Receiving psychotropic medications, receiving any antidepressants during past one month or ECT in past two months, Presence of hypothyroidism or cardiovascular problems
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
2-3
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
Tehran University of Medical Sciences
Street address
Keshavarz Blvd
City
Tehran
Postal code
Approval date
2007-04-20, 1386/01/31
Ethics committee reference number
5402

Health conditions studied

1

Description of health condition studied
Depressive episode
ICD-10 code
F32
ICD-10 code description
Depressive episode

Primary outcomes

1

Description
Severity of depression
Timepoint
Baseline and weeks 2,4 and 6
Method of measurement
Hamiltion Depression Rating Scale 17-Item

Secondary outcomes

empty

Intervention groups

1

Description
Capsule Fluoxetine 40 mg/day plus Capsule Celecoxib 400 mg/day (200 mg bid) as intervention group for 6 weeks
Category
Treatment - Drugs

2

Description
Cap fluoxetine 40 mg/day plus Cap. placebo as control group for 6 weeks
Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Psychiatry Hospital
Full name of responsible person
Dr. Sara Jafari
Street address
Roozbeh Hospital
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
Keshavarz Blvd
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Grant name
Grant code / Reference number
5402
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
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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