Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Randomized, Double-blind, Placebo-controlled trial of Celecoxib augmentation of Sertraline in treatment of Drug-Naïve depressed women

Protocol summary

Summary

The present study was designed to evaluate the therapeutic effect of COX-2 inhibitor Celecoxib (200 mg/day) as an augmentation therapy in the treatment of drug naïve depressed women. All patients (n=40) were women experiencing first episode of depression according to DSM-IV-TR. None of them had previously received antidepressant treatment and the Hamilton rating scale (17 items) score was ranged from 18 to 36. Patients with history of taking antidepressant medications, other psychiatric disorders, significant suicidal ideation, Liver and kidney dysfunction and cardiovascular disorders were excluded. Patients randomly received 25-100 mg/day Sertraline plus 100mg Celecoxib or placebo twice daily. Participants were assessed by Hamilton depression and anxiety rating scale and general health questionnaire at baseline, 4 and 8 weeks of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009043106N3**
Registration date: **2010-11-14, 1389/08/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-11-14, 1389/08/23

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

Country

Iran (Islamic Republic of)

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+98 21 2260 0037

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Recruitment status

Recruitment complete

Funding source

Pharmaceutical Sciences Branch of Islamic Azad University & Personal resources

Expected recruitment start date

2008-07-22, 1387/05/01

Expected recruitment end date

2010-06-20, 1389/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized, Double-blind, Placebo-controlled trial of Celecoxib augmentation of Sertraline in treatment of Drug-Naïve depressed women

Public title

Celecoxib add on therapy in drug naive depressed women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. women experiencing first episode of depression according to DSM-IV-TR and the Hamilton rating scale (17 items) score was ranged from 18 to 36. 2. None of them had previously received antidepressant treatment. Exclusion criteria: 1. History of taking antidepressant medications. 2. Other psychiatric disorders. 3. Significant suicidal ideation. 4. lactation and

pregnancy. 5. Liver and kidney dysfunction and cardiovascular disorders. 6. Drug abuse.

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
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
Pharmaceutical sciences branch of Islamic Azad university

Street address
No.99, Yakhchal street, Dr. Shariati Avenue

City
Tehran

Postal code

Approval date
2010-11-04, 1389/08/13

Ethics committee reference number
4114

Health conditions studied

1

Description of health condition studied
major depressive disorder

ICD-10 code
F32

ICD-10 code description
Depressive episode

Primary outcomes

1

Description
depression severity

Timepoint
baseline, week 4 and week 8

Method of measurement
Hamilton Depression rating scale -17 items

2

Description
anxiety severity

Timepoint
baseline, week 4 and week 8

Method of measurement
Hamilton Anxiety rating scale

Secondary outcomes

1

Description
general health level

Timepoint
baseline, week 4 and week 8

Method of measurement
General health questionnair-28

Intervention groups

1

Description
Celecoxib group: 25-100mg/day Sertraline plus 100mg Celecoxib twice daily for eight weeks.

Category
Treatment - Drugs

2

Description
Control group: 25-100mg/day Sertraline plus 100mg placebo twice daily for eight weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Zafar clinic

Full name of responsible person
Dr. Ali Sharifi

Street address

City
Tehran

2

Recruitment center
Name of recruitment center
Farshchian hospital
Full name of responsible person
Dr.Seyed Mohammad Hossini
Street address
City
Hamedan

3

Recruitment center
Name of recruitment center
Shahid Lavasani hospital
Full name of responsible person
Dr. Maryam Vahdat Shariat-panahi
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pharmaceutical Sciences Branch of Islamic Azad university
Full name of responsible person
Dr. Orkideh G. Dadras
Street address
Shariatee Ave. Yakhchal Str.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pharmaceutical Sciences Branch of Islamic Azad university
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
Pharmaceutical sciences branch of Islamic Azad university
Full name of responsible person
Dr. Farshad Hashemian
Position
assistant professor/clinical pharmacist
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact

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