

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 21 2260 0037

Email address

hashemian.f@iaups.ac.ir

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 questionnaire-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

Street address

No.99, Yakhchal strteet, Dr. Shariati Avenue

City

Tehran

Postal code

Phone

+98 21 2260 0037

Fax

+98 21 8857 7961

Email

hashemian.f@iaups.ac.ir , fhashemian@yahoo.com

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