Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A double-blind placebo controlled trial of celecoxibe added to sertralin in patients with moderate to severe depression

Protocol summary

Summary

According to DSM IV, participant with the diagnosis of Major Depression whose score of deppression according to Hamilton Depression Scale (HamD) would not be more than 22 will be included. Psychotic disorders and other diagnosis would be excluded. They should not be on antipsychotic or antidepressant (during the last month) drugs. In addition, they should not receive ECT. Patients have to be free of thyroid disease and they should be between 18-50 years old. They have to be free from cardiovascular disorders and ECG will be taken from those who suspicious to heart disease. Pregnant ladies and breast feeding mothers would be excluded from the study. Informed consent will be taken from all of the participants. Participants will divided into two groups. First group will receive Serteralin (200 mg/d) + Celexibe (200 mg BID) for 6 weeks. Second group will receive Serteralin (200 mg/d) + Placebo for 6 weeks. Then Patients will be followed at 0, 2, 4, and 6 months intervals according to the Hamilton Depression Scale (Ham D). Final results will be added to the same research which is running at Tehran University of Medical Sciences and analysis will be done then.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903124090N1**
Registration date: **2010-09-01, 1389/06/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-09-01, 1389/06/10

Registrant information

Name
Seyed Hesameddin Abbasi
Name of organization / entity
Tehran Heart Center
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
National Iranian Oil Company Health Organization

Expected recruitment start date

2010-06-15, 1389/03/25

Expected recruitment end date

2010-09-15, 1389/06/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double-blind placebo controlled trial of celecoxibe added to sertralin in patients with moderate to severe depression

Public title

Effect of celecoxibe added to sertralin in patients with moderate to severe depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1. Major Depression according to DSM IV and Hamilton Depression Scale(HamD) 2. 18 y < age > 50 y Exclusion Criteria: 1. Having psychotic disorders 2. Receiving anti-depressant drugs during last month 3.

Receiving ECT during last two months 4. Having thyroid disorder 5. Having Cardiovascular disorders 6. Pregnancy 7. Breast Feeding 8. Age <18 y 9. Age > 50 y

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

Gender
Both

Phase
1

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
Tehran University of Medical Sciences

Street address
Keshavarz Boulevard

City
Tehran

Postal code

Approval date
2017-02-21, 1395/12/03

Ethics committee reference number
5402

Health conditions studied

1

Description of health condition studied
Major Depression

ICD-10 code
F32.2

ICD-10 code description
Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description
Depression

Timepoint
0, 2, 4, 6 weeks intervals

Method of measurement
Hamilton depression scale

Secondary outcomes

1

Description
Antidepressants and Celxocibe side effects

Timepoint
0, 2, 4 and 6 weeks intervals

Method of measurement
drug side effects check list

Intervention groups

1

Description
Case group will receive Serteralin (200 mg/d) + Celexibe (200 mg BID) for 6 weeks.

Category
Placebo

2

Description
Control group will receive Serteralin (200 mg/d) + Placebo for 6 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
NIOC Central Hospital and Roozbeh Hospital

Full name of responsible person
Professor Shahin Akhondzadeh

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Iranian Oil Company Health Organization

Full name of responsible person
Dr. Farzaneh Torkan

Street address
Hafez Street, Sakhaee Street, NIOC Central Hospital

City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Iranian Oil Company Health Organization
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
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Person responsible for updating data

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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