# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Jul 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)

**Phone**

+98 21 8802 9720

**Email address**

abbasi@tehranheartcenter.org

**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**
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**Full name of responsible person**
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## Person responsible for scientific inquiries

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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*