

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Rosiglitazone as an adjunctive therapy in the treatment of patients with moderate to severe major depressive disorder: A randomized double-blind placebo-controlled clinical trial

#### Protocol summary

##### Study aim

Evaluating the effect of Rosiglitazone in the treatment of depression

##### Design

Randomized double blind and placebo-controlled clinical trial

##### Settings and conduct

This study will be performed on patients attending Roozbeh Hospital

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosed with major depressive disorder (MDD) based on DSM5 - Depression severity should be above 22 according to the Hamilton Depression Scale - Age between 18-60. Exclusion criteria: Psychotic patients - Diagnosis of any disturbances in other axes - The use of psychoactive drugs - The use of antidepressants in the last one month or ECT in the last two months - History of cardiovascular disease (EKG can be taken, and if there is a problem in the function of heart, the patient is excluded from the study) - Thyroid problems - Pregnant and lactating women

##### Intervention groups

Control group: Sertraline (100 mg/day) and placebo for six weeks. Intervention group: Sertraline (100 mg/day) and Rosiglitazone (2 mg, twice a day) for six weeks.

##### Main outcome variables

Depression severity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090117001556N152**

Registration date: **2023-06-20, 1402/03/30**

Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

##### Registration date

2023-06-20, 1402/03/30

##### Registrant information

###### Name

Shahin Akhondzadeh

###### Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5541 2222

###### Email address

s.akhond@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2025-07-23, 1404/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Rosiglitazone as an adjunctive therapy in the treatment of patients with moderate to severe major depressive disorder: A randomized double-blind placebo-controlled clinical trial

##### Public title

The effect of Rosiglitazone in the treatment of depression

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Diagnosed with major depressive disorder (MDD) based on DSM5 Depression severity should be above 22 according to the Hamilton Depression Scale Age between 18-60

#### **Exclusion criteria:**

Psychotic patients Diagnosis of any disturbances in other axes The use of psychoactive drugs The use of antidepressants in the last one month or ECT in the last two months History of cardiovascular disease (EKG can be taken, and if there is a problem in the function of heart, the patient is excluded from the study) Thyroid problems Pregnant and lactating women

### **Age**

From **18 years** old to **60 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

### **Sample size**

Target sample size: **50**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups).

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of School of Medicine, Tehran University of Medical Sciences

##### **Street address**

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1417653761

##### **Approval date**

2023-04-14, 1402/01/25

##### **Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1402.150

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Major depressive disorder

#### **ICD-10 code**

F32

#### **ICD-10 code description**

Major depressive disorder, single episode

## **Primary outcomes**

### **1**

#### **Description**

Severity of depression

#### **Timepoint**

Weeks: 0-2-4-6

#### **Method of measurement**

by Hamilton Depression Rating Scale

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Control group: Sertraline (100 mg/day) and placebo for six weeks.

#### **Category**

Placebo

### **2**

#### **Description**

Intervention group: Sertraline (100 mg/day) and Rosiglitazone (2 mg, twice a day) for six weeks.

#### **Category**

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Roozbeh hospital

**Full name of responsible person**

Dr. Mohammad Reza Mohammadi

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1333715914

**Phone**

+98 21 5541 2222

**Email**

mohammadimr@tums.ac.ir

## 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.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 5541 2222

**Email**

afotouhi@tums.ac.ir

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**
**Type of organization providing the funding**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Shahin Akhondzadeh

**Position**

Professor of clinical psychopharmacology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Shahin Akhondzadeh

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## Person responsible for updating data

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The data will be distributed through final report

**When the data will become available and for how long**

5 years from 2023 to 2028

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Users should cite the resource of data

**From where data/document is obtainable**

Prof. Shahin Akhondzadeh

**What processes are involved for a request to access data/document**

By e-mail

**Comments**