Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Hamiltion 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

Treatment - Drugs

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

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Tehran

Province
Tehran

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1333715914

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+98 21 5541 2222

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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
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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
Academic

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

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Roozbeh Hospital, South Kargar Street, Tehran

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Person responsible for updating data

Contact

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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