

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

pioglitazone as adjuvant therapy in the treatment of major depression: a randomised and double blind study

Protocol summary

Summary

The purpose of the present investigation is to assess the efficacy of Pioglitazone as an adjuvant agent in the treatment of major depression in a six-week double-blind, placebo controlled trial. 40 adult outpatients who meet the DSM- IV-TR criteria for major depression will participate in the trial. Patients who have a baseline Hamilton Rating Scale for Depression score of at least 22 will be allocated into two groups. 20 patients will receive Citalopram 40 mg/day plus Pioglitazone 30mg/day and 20 participants will receive Citalopram 40 mg/day plus placebo. Patients were assessed by a psychiatrist at baseline and after 2, 4 and 6 weeks after the medication started. Depression severity will be assessed by Hamilton Depression Rating Scale which will be the primary outcome measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012031556N20**

Registration date: **2010-12-04, 1389/09/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-04, 1389/09/13

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

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Recruitment status

Recruitment complete

Funding source

1-Tehran University of Medical Sciences 2-Kurdistan University of Medical Sciences-Sanandaj-Iran

Expected recruitment start date

2010-04-06, 1389/01/17

Expected recruitment end date

2011-10-06, 1390/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

pioglitazone as adjuvant therapy in the treatment of major depression: a randomised and double blind study

Public title

Pioglitazone in the treatment of major depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of Major Depressive Disorder based on DSM-IV criteria, Baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 22.

Exclusion criteria: Presence of Psychosis, any other diagnosis in Axis I and II, Receiving psychotropic medications, receiving any antidepressants during past one month or ECT during past two months, Presence of hypothyroidism or cardiovascular problems, pregnancy or nursing women

Age

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

Gender

Both

Phase

2-3

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**

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd

City

Tehran

Postal code**Approval date**

2010-03-06, 1388/12/15

Ethics committee reference number

9476

Health conditions studied**1****Description of health condition studied**

Major Depressive episode

ICD-10 code

F32

ICD-10 code description

Major Depressive episode

Primary outcomes**1****Description**

Severity of depression

Timepoint

Baseline and weeks 2,4 and 6

Method of measurement

Hamilton Depression Rating Scale 17-Item

Secondary outcomes

empty

Intervention groups**1****Description**

Tablet Citalopram 40 mg/day plus Tablet Pioglitazone30 mg/day as intervention group for 6 weeks

Category

Treatment - Drugs

2**Description**

Tablet Citalopram 40 mg/day plusTablet placebo as control group for 6 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Roozbeh Hospital

Full name of responsible person

Prof. Shahin Akhondzadeh

Street address

Roozbeh Hospital

City

Tehran

2**Recruitment center****Name of recruitment center**

Qhods Hospital- Kurdistan University of Medical Sciences

Full name of responsible person

Dr. Farzin Rezaei

Street address

Pasdaran Blvd- Qhods hospital - Sanandaj

City

Sanandaj

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
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Tehran University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
 Kurdistan University of Medical Sciences
Full name of responsible person
 Dr Ataollah Heydari
Street address
 Pasdaran Blvd-Kurdistan university of Medical Sciences-Deputy of research- Sanandaj
City
 Sanandaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Kurdistan University of Medical Sciences
Proportion provided by this source
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

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Web page address

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