

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the efficacy of gemfibrozil as an adjunct therapy in improving the symptoms of major depressive disorder; A double-blind, placebo-controlled trial

#### Protocol summary

##### Study aim

The objective of this study is to assess the efficacy of Gemfibrozil in the treatment of MDD

##### Design

Randomized double blind and placebo-controlled clinical trial

##### Settings and conduct

The study will be conducted among adults with major depressive disorder attending Roozbeh Hospital and Imam-Hossein Hospital(in Karaj).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: presence of Major Depressive Disorder based on DSM-5 criteria; baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 22  
Exclusion criteria: presence of psychosis, any other mental disorder; substance dependence(except for Nicotine and caffeine); IQ lower than 70;significant neurologic or medical disease; history of cholelithiasis; receiving Warfarin; receiving Insulin; receiving Statins; receiving Niacin

##### Intervention groups

The participants will be randomly allocated into two groups. Intervention group(20 persons) will receive gemfibrozil (300 mg per day) and sertraline ( 100 mg per day) for 8 weeks and control group ( 20 persons) will receive sertraline ( 100 mg per day) for 8 weeks.

##### Main outcome variables

Severity of depression

#### General information

##### Reason for update

change the dosage

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090117001556N119**  
Registration date: **2019-03-17, 1397/12/26**

Registration timing: **prospective**

Last update: **2020-03-27, 1399/01/08**

Update count: **1**

##### Registration date

2019-03-17, 1397/12/26

##### 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

2019-04-05, 1398/01/16

##### Expected recruitment end date

2021-04-04, 1400/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the efficacy of gemfibrozil as an adjunct therapy in improving the symptoms of major depressive disorder; A double-blind, placebo-controlled trial

**Public title**

Evaluation of the efficacy of gemfibrozil as an adjunct therapy in improving the symptoms of major depressive disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Presence of Major Depressive Disorder based on DSM-5 criteria Baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 22 Age between 18 to 60 years

**Exclusion criteria:**

Presence of psychosis Substance use disorder except for nicotine and caffeine IQ lower than 70 Any other mental disorder Any significant neurologic or medical disease(advanced renal disease, CKD, hepatic disease, cardiovascular disease) history of cholelithiasis Receiving Warfarin Receiving Insulin Receiving statins Receiving niacin

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random permuted block

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The participants, clinicians and outcome raters will be blind regarding grouping

**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**

Tehran University of Medical Sciences, Keshavarz Blv

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2019-03-08, 1397/12/17

**Ethics committee reference number**

IR.TUMS.VCR.REC.1397.880

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

Major Depressive Disorder

**ICD-10 code**

F32.2

**ICD-10 code description**

Major depressive disorder, single episode, severe without psychotic features

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

Severity of depression

**Timepoint**

Baseline and weeks 2,4 and 8

**Method of measurement**

by Hamilton Depression Rating Scale 17-Item

**Secondary outcomes**

empty

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

Intervention group: tablet sertraline 100 mg/day plus Capsule gemfibrozil 300 mg per day as intervention group for 8 weeks

**Category**

Treatment - Drugs

**2****Description**

Control group: tablet sertraline 100 mg/day plus Capsule placebo as control group for 8 weeks

**Category**

Placebo

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Roozbeh Hospital

**Full name of responsible person**

Dr. Shahin Akhondzadeh

**Street address**

Roozbeh Hospital , South Kargar Sreet

**City**

Tehran

**Province**

Tehran

**Postal code**

1333715914

**Phone**

+98 21 5541 2222

**Email**

s.akhond@sina.tums.ac.ir

## 2

### Recruitment center

**Name of recruitment center**

Imam Hossein Hospital

**Full name of responsible person**

Dr Atefeh Zandi Far

**Street address**

Imam Hossein Hospital, 104th Street, Imam Khomeini Blvd., Mohammad Shahr

**City**

Tehran

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**Postal code**

3184669519

**Phone**

+98 26 3620 9063

**Email**

zandifar@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Ali Sahraian

**Street address**

Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 8898 7381

**Email**

msahrai@tums.ac.ir

**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**

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**

Prof. 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,

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor of clinical psychopharmacology

**Latest degree**

Ph.D.

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**Email**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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**Province**

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**Postal code**

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**Phone**

+98 21 5541 2222

**Fax****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**

No - There is not 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 2021 to 2026

**To whom data/document is available**

Academic researchers

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

by citing the resource

**From where data/document is obtainable**

Professor Shahin Akhondzadeh

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

by E mail

**Comments**