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

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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 Substanse 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 Recieving 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 Hamiltion Depression Rating Scale 17-Item

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: tablet sertralin 100 mg/day plus Capsule gemfibrozil 300 mg per day as intervention group for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: tablet sertralin 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
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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address

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 resourse
From where data/document is obtainable
Professor Shahin Akhondzadeh
What processes are involved for a request to access data/document
by E mail
Comments