Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

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

Protocol summary

Study aim
The objective of this study is to assess the efficacy of pentoxifylline 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.

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 19.
Exclusion criteria: presence of psychosis, any other mental disorder; presence of hypothyroidism or cardiovascular problems; pregnancy or nursing women; hepatic failure; peptic ulcer; receiving antiplatelets agents or anticoagulants; receiving NSAIDs.

Intervention groups
The participants will be randomly allocated into two groups. Intervention group(25 persons) will receivepentoxyfylline (400 mg TDS) and sertraline (50 mg per day) and control group (25 persons) will receive sertraline (50 mg per day) for 6 weeks.

Main outcome variables
Severity of depression

General information

Reason for update
Change in the dosage of Serteralin from 50 mg to 100 mg

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N116**
Registration date: **2019-03-14, 1397/12/23**
Registration timing: **prospective**
Last update: **2020-08-25, 1399/06/04**
Update count: **1**

Registration date
2019-03-14, 1397/12/23

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
2019-04-13, 1398/01/24

Expected recruitment end date
2021-04-12, 1400/01/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

Public title
Pentoxifylline as adjuvant therapy in the treatment of major depression

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 19

Exclusion criteria:

Presence of psychosis Any other mental disorder Hypothyroidism Cardiovascular disease Pregnancy or nursing women Renal failure Allergy to Theophylline, Aminophylline, and pentoxyfylline Hepatic failure Peptic ulcer Receiving antiplatelets agents or anticoagulants Receiving NSAIDs

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.TUMS.VCR.REC.1397.1006

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

Primary outcomes

1

Description

Severity of depression

Timepoint

Baseline and weeks 2,4 and 6

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 pentoxyfylline 400 mg TDS as intervention group for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: tablet sertralin 100 mg/day plus Capsule placebo as control group for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran hospital

Full name of responsible person

Dr Mohammad-Reza Shalbafan

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN

City
Tehran
Province
Tehran
Postal code
1398913151
Phone
+98 21 4450 3395
Email
shalbafan@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
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,
City
Tehran
Province
Tehran
Postal code
1333715914
Phone
+98 21 5541 2222
Fax
+98 21 5541 9113
Email
s.akhond@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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
City
Tehran
Province
Tehran
Postal code
1333715914
Phone
+98 21 5541 2222
Email
s.akhond@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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
City
Tehran
Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 2222

Fax

+98 21 5541 9113

Email

s.akhond@sina.tums.ac.ir

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