

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Investigating the effect of Pentoxifylline for the treatment of mild to moderate major depression in cardiovascular patients after PCI or CABG

Protocol summary

Study aim

The effect of Pentoxifylline for the treatment of mild to moderate major depression in cardiovascular patients after PCI or CABG

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

The study will be conducted among patients with major depressive disorder attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of mild to moderate major depressive disorder, based on DSM-5. Score between 14 to 17, based on Hamilton depression scale. Age between 40 to 60 years. Having heart disease undergoing PCI or CABG. Exclusion criteria: Drug use during 1 year prior to trial. Presence of concomitant psychiatric disorders. Pregnant or lactating women. History of Electroconvulsive therapy, two months prior to the trial. Psychosis. Thyroid disorders. The patient's own request to leave the study.

Intervention groups

Patients with major depression (based on DSM-5 diagnostic criteria) are included in the study and divided into two control (25 participants) and intervention (25 participants) groups. Patients in the intervention group receive Pentoxifylline tablet 800mg per day for 6 weeks and patients in the control group receive placebo tablet for 6 weeks. Patients are evaluated at weeks 0, 2, 4, and 6 by the Hamilton Depression Rating Scale.

Main outcome variables

Severity of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N132**

Registration date: **2020-08-26, 1399/06/05**

Registration timing: **prospective**

Last update: **2020-08-26, 1399/06/05**

Update count: **0**

Registration date

2020-08-26, 1399/06/05

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

2020-09-10, 1399/06/20

Expected recruitment end date

2022-09-11, 1401/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Pentoxifylline for the treatment of mild to moderate major depression in cardiovascular patients after PCI or CABG

Public title

The effect of Pentoxifylline for the treatment of major depression in cardiovascular patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of mild to moderate major depressive disorder, based on DSM-5 Score between 14 to 17, based on Hamilton depression scale Age between 40 to 60 years Having heart disease undergoing PCI or CABG

Exclusion criteria:

Drug use during 1 year prior to trial Presence of concomitant psychiatric disorders Pregnant or lactating women History of Electroconvulsive therapy, two months prior to the trial Psychosis Thyroid disorders The patient's own request to leave the study

Age

From **40 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 interventions in 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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-08-18, 1398/05/27

Ethics committee reference number

IR.TUMS.VCR.REC.1398.699

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 6

Method of measurement

By Hamilton depression scale

Secondary outcomes

empty

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

Intervention group: Pentoxifylline tablet (Farabi co.) 800mg per day for 6 weeks

Category

Treatment - Drugs

2**Description**

Control group: placebo tablet per day for 6 weeks

Category

Placebo

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Prof. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

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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

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

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Person responsible for scientific inquiries

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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 2021 to 2026

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