Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Cilostazol for depressive disorder after percutaneous coronary intervention or coronary-artery bypass grafting: A randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim
Evaluating the effect of Cilostazol for major depressive disorder after percutaneous coronary intervention or coronary-artery bypass grafting

Design
Randomized double blind and placebo-controlled clinical trial. Patients are randomly divided (with allocation ratio 1:1) into two groups of Cilostazol or placebo based on blocks of 4 using the computerized randomization list.

Settings and conduct
This study will be performed on patients attending Roozbeh Hospital or Imam Khomeini Hospital. Patients who meet the inclusion and exclusion criteria will be included. Patients will receive Cilostazol (100 mg tablets) or placebo for six weeks, both of which will look exactly the same.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with coronary artery disease who underwent elective percutaneous coronary intervention or coronary-artery bypass grafting in the past three months due to angina pectoris or left ventricular dysfunction not associated with myocardial infarction. Diagnosis of major depressive disorder based on DSM-V (score between 14 and 17). Age between 40-60. Exclusion criteria: Patients who have taken antipsychotic drugs in the last year. Diagnosis of other psychiatric disorders. Electroconvulsive treatment in the last two months. History of thyroid disease. Inflammatory diseases, including autoimmune thyroiditis, inflammatory bowel disease, systemic lupus erythematosus, psoriasis, autoimmune hepatitis, migraine, Guillain-Barre syndrome, multiple sclerosis, and rheumatoid arthritis. Being pregnant or breastfeeding. History of allergy to Cilostazol. Simultaneous need for antithrombin alpha, antithrombin III, argatroban, enoxaparin, apixaban, and other drugs with severe interaction with Cilostazol.

Intervention groups
Control group: placebo for 6 weeks. Intervention group: Cilostazol (100 mg per day) for 6 weeks.

Main outcome variables
Depression severity

General information

Reason for update
end of trial

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N154**
Registration date: **2023-11-05, 1402/08/14**
Registration timing: **prospective**

Last update: **2024-09-19, 1403/06/29**
Update count: **1**

Registration date
2023-11-05, 1402/08/14

Registrant information

Name
Shahin Akhondzadeh

Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-06-21, 1403/04/01
Actual recruitment start date
2023-12-22, 1402/10/01
Actual recruitment end date
2024-06-10, 1403/03/21
Trial completion date
2024-06-21, 1403/04/01

Scientific title
Cilostazol for depressive disorder after percutaneous coronary intervention or coronary-artery bypass grafting: A randomized, double-blind, placebo-controlled trial

Public title
Cilostazol for the treatment of depression in cardiac patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with coronary artery disease who underwent elective percutaneous coronary intervention or coronary-artery bypass grafting in the past three months due to angina pectoris or left ventricular dysfunction not associated with myocardial infarction. Diagnosis of major depressive disorder based on DSM-V (score between 14 and 17). Age between 40-60.
Exclusion criteria:
Patients who have taken antipsychotic drugs in the last year. Diagnosis of other psychiatric disorders. Electroconvulsive treatment in the last two months. History of thyroid disease. Inflammatory diseases, including autoimmune thyroiditis, inflammatory bowel disease, systemic lupus erythematosus, psoriasis, autoimmune hepatitis, migraine, Guillain-Barre syndrome, multiple sclerosis, and rheumatoid arthritis. Being pregnant or breastfeeding. History of allergy to Cilostazol. Simultaneous need for antithrombin alpha, antithrombin III, argatroban, enoxaparin, apixaban, and other drugs with severe interaction with Cilostazol.
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**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted block randomization: using A and B 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 School of Medicine, Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Pour Sina St., Qods St., Enghelab St.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2023-10-10, 1402/07/18
Ethics committee reference number
IR.TUMS.IKHC.REC.1402.291

Health conditions studied

1

Description of health condition studied
depressive disorder
ICD-10 code
F32
ICD-10 code description
depressive disorder, single episode

Primary outcomes

1

Description
Severity of depression
Timepoint
Weeks: 0-2-4-6

Method of measurement
By Hamilton Depression Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: placebo for 6 weeks.
Category
Placebo

2

Description
Intervention group: Cilostazol (100 mg per day) for 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh hospital
Full name of responsible person
Dr. 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. Akbar Fotouhi
Street address
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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
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
Dr. Shahin Akhondzadeh
Position
Professor of clinical psychopharmacology
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Roozbeh Hospital, South Kargar Street, Tehran.
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Person responsible for scientific inquiries

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Full name of responsible person
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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 2023 to 2028.

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
Those who are interested can send their request to receive the documents and methods related to the research by email to Dr. Shahin Akhondzadeh.

What processes are involved for a request to access data/document
By e-mail: s.akhond@sina.tums.ac.ir

Comments