

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Sulforaphane as a treatment for mild to moderate depression in post percutaneous coronary intervention patients: A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim

Studying the effect of Sulforaphane on the treatment of mild to moderate depression in post percutaneous coronary intervention patients

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

The study will be performed on patients with heart disease who underwent percutaneous coronary intervention, and with mild to moderate depression attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: based on DSM-5 diagnostic criteria, have minor depression disorder; based on Hamilton depression scale, get the score of 14 to 17; age between 18 to 50 years old; history of percutaneous coronary intervention. Exclusion criteria: pregnant or lactating women; presence of other psychiatric disorders; be psychotic; history of Electroconvulsive therapy; two months prior to the trial; using psychotropic drug; drug addiction; presence of thyroid disease.

Intervention groups

Patients with mild to moderate 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 Sulforaphane tablet for 6 weeks, and patients in the control group receive placebo for 6 weeks. Patients are assessed at weeks 0, 2, 4, and 6 by Hamilton depression scale. Side effects of the drug are assessed at weeks 1, 2, 4 and 6.

Main outcome variables

Severity of depression

General information

Reason for update

We have to find older patients

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N128**

Registration date: **2020-05-19, 1399/02/30**

Registration timing: **prospective**

Last update: **2021-01-02, 1399/10/13**

Update count: **1**

Registration date

2020-05-19, 1399/02/30

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

2020-06-21, 1399/04/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Sulforaphane as a treatment for mild to moderate depression in post percutaneous coronary intervention patients: A randomized double blind and placebo controlled clinical trial

Public title
The effect of Sulforaphane on the treatment of mild to moderate depression in post percutaneous coronary intervention patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Based on DSM-5 diagnostic criteria, have minor depression disorder Based on Hamilton depression scale, get the score of 14 to 17 Age between 40 to 65 years History of percutaneous coronary intervention
Exclusion criteria:
 Pregnant or lactating women Presence of other psychiatric disorders Be psychotic History of Electroconvulsive therapy, two months prior to the trial Using psychotropic drug Drug addiction Presence of Thyroid disease

Age
From **40 years** old to **65 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 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, Qhods St., Keshavarz Blvd.
City
 Tehran
Province
 Tehran
Postal code
 1417653761
Approval date
 2019-12-22, 1398/10/01
Ethics committee reference number
 IR.TUMS.VCR.REC.1398.1004

Health conditions studied

1

Description of health condition studied
 Depression
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 Hamilton depression scale

Secondary outcomes
empty

Intervention groups

1

Description
 Intervention group: Sulforaphane tablet (ACECR, Tehran), 30 mg per day for 6 weeks

Category

Treatment - Drugs

2**Description**

Control group: Placebo, once a day for 6 weeks

Category

Placebo

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

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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****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

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Person responsible for updating data

Contact

Name of organization / entity

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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