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
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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
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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
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Person responsible for updating data

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Position
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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