

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

the effect of garlic supplementation therapy on the rate of atherosclerosis change in coronary arteries in ischemic heart disease patients

Protocol summary

Study aim

The effect of garlic supplementation on changes in coronary atherosclerosis in cardiac ischemia patients

Design

Patients in both groups were blind in terms of the type of intervention given the similar form of medication and the physician would not be aware of the type of treatment. Medication information will be tracked and coded. Blinding or blinding will be done by the researcher and medications will be given by the nurse in charge of the patient's delivery department.

Settings and conduct

patients referring to cardiology and angiography ward of Kashan Shahid Beheshti Hospital and will be enrolled in the study as an informed consent trial. Individuals will be divided into two groups according to the randomization block method.

Participants/Inclusion and exclusion criteria

All patients with coronary artery stenosis will be enrolled after angiography with stenosis greater than or equal to 60% in at least two veins. These included patients admitted to MI and ACS and patients with stable angina who were candidates for angiography and, according to the observation physician, were candidates for two or more angioplasty in two sessions. The percentage of stenosis in the vessels involved is initially determined and in the first session of one of the vessels angioplasty is performed and before the second angioplasty the patients are randomly divided into control and intervention groups

Intervention groups

In a group of 8 weeks between two angiograms in addition to standard drug administration (statin, ASA, clopidogrel, hypertension medication) by a physician, 2 garlic pills daily will given to patients containing 300 mg of dried garlic powder from the company of Gul Darou.

Main outcome variables

Blood tests for CBC, TG, Chol, LDL, HDL, FBS, Hba1c, CRP, Cr and blood pressure and then for angioplasty will also be recorded by QCA angiography for coronary stenosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191113045431N1**
Registration date: **2020-01-17, 1398/10/27**
Registration timing: **prospective**

Last update: **2020-01-17, 1398/10/27**

Update count: **0**

Registration date

2020-01-17, 1398/10/27

Registrant information

Name

sajjad zarrati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0139

Email address

sajjad.zarrati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-05-01, 1399/02/12

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
the effect of garlic supplementation therapy on the rate of atherosclerosis change in coronary arteries in ischemic heart disease patients

Public title
the effect of garlic on the rate of atherosclerosis change in coronary arteries

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patient who have two or more obstruction in coronary arteries Patient who have only one PCI on coronary artery in one operation Patient who is reliable to follow his medication
Exclusion criteria:
Patient who are hypersensitive to garlic

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
block randomized manner using the random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo and medicines are packaged and coded. The caregiver delivers them to the patients without knowing the contents of the package. Patients also don't know the content of packages. Information is also collected without knowing the contents of the packages.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kashan University of Medical Sciences

Street address

ghotb ravandi Blvd, pezeshek Blvd, kashan university of medical science

City

kashan

Province

Isfahan

Postal code

8715973474

Approval date

2018-08-13, 1397/05/22

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.036

Health conditions studied

1

Description of health condition studied

Atherosclerotic heart disease

ICD-10 code

I25.10

ICD-10 code description

Atherosclerotic heart disease of native coronary artery without angina pectoris

Primary outcomes

1

Description

Percentage of coronary artery stenosis

Timepoint

Measurement on two occasions of angioplasty for at least 8 weeks

Method of measurement

Measurement of QCA by angiography device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In 8 weeks between two angiograms in addition to standard drug (statin, ASA, clopidogrel, hypertension medication), administration by a physician, 2 garlic pills daily containing 300 mg of dried garlic powder from the company of Gul Darou and two grams of garlic equivalent, Will be given

Category

Treatment - Drugs

2

Description

Control group: Patients who did not receive garlic tablets between two angiography sessions

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti hospital

Full name of responsible person

Dr Hasan Rajabimoghadam

Street address

Ghotb ravandi Blvd, Pezeshk Blvd, Shahid Beheshti Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Hamidreza Banafshe

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Sajjad Zarrati

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Sajjad Zarrati

Position

Intern

Latest degree

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the main outcome data

When the data will become available and for how long

Start access period concurrently with release

To whom data/document is available

Everyone

Under which criteria data/document could be used

No special conditions

From where data/document is obtainable

Send responsible email

What processes are involved for a request to access data/document

Request via email and then send it after viewing the email

Comments