

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Ginger (*Zinger officinale* Roscoe) on clinical symptoms in patients with slow coronary flow on angiography

#### Protocol summary

##### Study aim

Effect of Ginger (*Zinger officinale* Roscoe) on clinical symptoms in patients with slow coronary flow on angiography

##### Design

Phase 2 randomized double-blinded placebo parallel clinical trial on 48 patients Randomization using Randaization.com

##### Settings and conduct

This study will perform in the heart ward and clinic of Ghaem Hospital in Mashhad. Patients are randomly assigned to Ginger and placebo groups. Patients and the main researcher are unaware of the group assignment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to admission to the study; Age more than 30 years old; Patients with slow coronary flow with a corrected TIMI frame count of more than 27 frames per second Exclusion criteria: Cardiovascular disease other than mild coronary atherosclerosis; congenital heart disease; stomach ulcers or duodenal ulcers; Taking anticoagulants such as warfarin, aspirin, and enoxaparin; Breastfeeding or pregnancy; consumption of omega-3 (fish oil), ciprofloxacin, loratadine, escitalopram, montelukast, and levothyroxine; kidney stone

##### Intervention groups

Intervention group: Patients with slow coronary disease receiving common treatments (including aspirin, statins, beta-blockers and ACEIs) + Ginger 250 mg once daily for one month Placebo group: Patients with slow coronary disease receiving common treatments + placebo tablet once daily for one month

##### Main outcome variables

Changes in the score of quality of life according to the EuroQoL-VAS (0-100; 100 is the best quality of life and 0 is the worst quality of life)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230625058582N1**

Registration date: **2023-07-29, 1402/05/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-07-29, 1402/05/07**

Update count: **0**

##### Registration date

2023-07-29, 1402/05/07

##### Registrant information

##### Name

Sara Afshar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3802 2000

##### Email address

afshars@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2025-07-23, 1404/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Ginger (Zinger officinale Roscoe) on clinical symptoms in patients with slow coronary flow on angiography

#### Public title

Effect of Ginger (Zinger officinale Roscoe) on patients with slow coronary flow

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Consent to admission to the study Age more than 30 years old Patients who have less than 50% stenosis in each of the 3 main coronary arteries in their coronary angiography and have delayed filling in at least one of the coronary arteries and have slow coronary flow in a corrected TIMI frame count of more than 27 frames per second

##### Exclusion criteria:

Stomach ulcers or duodenal ulcers Taking anticoagulants such as warfarin, aspirin and enoxaparin Breastfeeding or pregnancy Consumption of omega 3 (fish oil), ciprofloxacin, loratadine, citalopram, montelukast, and levothyroxine Kidney stone History of known congenital heart disease History of any cardiovascular diseases other than mild coronary atherosclerosis

#### Age

From 30 years old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: 48

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The blocked randomization method is used. The volume of each block will be four. Then the list of blocks is written and numbers assigned to them, for example (AABB(1)- BBAA(2)- BABA(3)- BAAB(4)), which will be 12 blocks according to the sample size of 48. Then random numbers between 1 and 12 are selected according to the randomization site Randomization.com and finally, the treatment allocation list is determined based on the random numbers.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Blinding is done using sealed envelopes. Furthermore, due to using a placebo similar to the intervention treatment, the investigator and the participants will not be informed of the assigned treatment, and the analyst will also be unaware of the assigned treatment for the two groups. Finally, after analyzing the data, the

researcher who prepared the packages will reveal the codes A and B.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Imam Reza Hospital Educational, Research and Treatment Center, Mashhad

##### Street address

Imam Reza Hospital educational complex building, Imam Reza Hospital, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

#### Approval date

2023-05-01, 1402/02/11

#### Ethics committee reference number

IR.MUMS.IRH.REC.1402.024

## Health conditions studied

### 1

#### Description of health condition studied

Coronary slow flow syndrome

#### ICD-10 code

I20.8

#### ICD-10 code description

Other forms of angina pectoris

## Primary outcomes

### 1

#### Description

Changes in the score of quality of life according to the EuroQoL-VAS scale (0-100; 100 is the best quality of life and 0 is the worst quality of life)

#### Timepoint

Before intervention and one month after beginning the intervention

#### Method of measurement

According to the EuroQoL-VAS scale (0-100; 100 is the best quality of life and 0 is the worst quality of life)

## Secondary outcomes

### 1

#### Description

Frequent pain during the day

#### Timepoint

Before intervention and one months after beginning the intervention

#### Method of measurement

Checklist

### 2

#### Description

Duration of pain in minutes

#### Timepoint

Before intervention and one months after beginning the intervention

#### Method of measurement

Checklist

### 3

#### Description

Quality of life according to Seattle Angina Questionare

#### Timepoint

Before intervention and one months after beginning the intervention

#### Method of measurement

Seattle Angina Questionare

## Intervention groups

### 1

#### Description

Intervention group: Patients with slow coronary artery disease receiving routine treatment (including aspirin, statins, beta-blockers and angiotensin-converting enzyme inhibitors) along with edible ginger rhizome powder at a dose of 250 mg once daily for one month

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients with slow coronary artery disease receiving routine treatment (including aspirin, statins, beta-blockers and angiotensin-converting enzyme inhibitors) along with placebo capsule with similar shape, size, and color once daily for one month. The placebo capsule contains 250 mg of Avicel® and is prepared by Dr. Askari's research laboratory at Mashhad University of Medical Sciences.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital in Mashhad

##### Full name of responsible person

Dr. Sara Afshar

##### Street address

Ghaem hospital, Ahmadabad Blvd, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3801 2739

##### Email

afshars@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Majid Ghayour-Mobarhan

##### Street address

Qurashi Building, Next to Hoveyzeh Cinema, University Street, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

Ramresearch@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Sara Afshar

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

**Street address**

Imam Reza hospital, Ebnsina Blvd

**City**

MASHHAD

**Province**

Razavi Khorasan

**Postal code**

۹۱۳۷۹۱۳۳۱۶

**Phone**

+98 51 3854 3031

**Fax****Email**

afshars@mum.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Sara Afshar

**Position**

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**Latest degree**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available