

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of Ginger (*Zinger officinale* Roscoe) on the prevention of PVC in patients with palpitation

Protocol summary

Study aim

The effects of Ginger (*Zinger officinale*) on the prevention of PVC in patients with palpitation

Design

Phase 2-3 randomized double-blinded placebo parallel clinical trial on 48 patients Randomization using RandoMaization.com

Settings and conduct

This study will perform in the heart ward and clinic of Imam Reza 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; Patients with heart palpitations; The number of PVCs during one day less than 15% in the 24-hour Holter rhythm. Not inclusion criteria: Previous history of heart palpitations; History of receiving medications for PVC ; Structural heart disorder; stomach ulcers or duodenal ulcers; Taking anticoagulants such as warfarin, aspirin, and enoxaparin; Breastfeeding or pregnancy; consumption of omega-3, ciprofloxacin, loratadine, escitalopram, montelukast, and levothyroxine; kidney stone; History of taking medicines containing ginger.

Intervention groups

Patients with heart palpitations receiving Ginger capsule (250 mg once daily) for ten days

Main outcome variables

Number of PVCs during 24 h

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054874N13**

Registration date: **2023-10-11, 1402/07/19**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-11, 1402/07/19**

Update count: **0**

Registration date

2023-10-11, 1402/07/19

Registrant information

Name

Vafa Baradaran Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2301

Email address

baradaranrv@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2025-10-07, 1404/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Ginger (*Zinger officinale* Roscoe) on the prevention of PVC in patients with palpitation

Public title

The effects of Ginger (*Zinger officinale* Roscoe) on the prevention of PVC in patients with palpitation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with heart palpitations The number of PVCs during one day less than 15% in the 24-hour Holter rhythm Consent to admission to the study;

Exclusion criteria:

Previous history of heart palpitations History of receiving medications for PVC Structural heart disorder 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 taking medicines containing ginger

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- 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

2023-04-10, 1402/01/21

Ethics committee reference number

IR.MUMS.IRH.REC.1402.005

Health conditions studied

1

Description of health condition studied

Palpitations

ICD-10 code

R00.2

ICD-10 code description

Palpitations

Primary outcomes

1

Description

The number of PVCs during 24 h

Timepoint

Before intervention and 10 days after beginning the intervention

Method of measurement

24-hour Holter rhythm

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with heart palpitations receiving capsule containing ginger rhizome powder at a dose of 250 mg once daily for 10 days.

Category

Treatment - Drugs

2

Description

Control group: Patients with heart palpitations receiving placebo capsule with similar shape, size, and color once daily for 10 days. 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**

Department of Cardiology, Imam Reza Hospital

Full name of responsible person

Dr. Sara Afshar

Street address

Imam Reza hospital, Ebnsina Blvd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mosen Tafaghodi

Street address

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

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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. Vafa Baradaran Rahimi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Ghaeem hospital, Ahmadabad Blvd, Mashhad

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr. Vafa Baradaran Rahimi

Position

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Person responsible for updating data

Contact

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Full name of responsible person

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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