

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effect of single dose administration of ginger on frequency domain heart rate variability measures in young healthy subjects

Protocol summary

Study aim

Effect of Ginger 250 mg capsule consumption on frequency domain heart rate variability measures in young healthy subjects

Design

Randomised, double-blind, phase 1, clinical trial with crossover placebo control to evaluate effect of single dose administration of ginger on frequency domain heart rate variability measures in young healthy subjects. A table of random numbers is used for randomisation.

Settings and conduct

In Rouhani Hospital, at the beginning of the intervention, 30 healthy young subjects between 19 to 26 years old with normal BMI will be given a pack with a three-digit code that contains Ginger 250 mg capsule or placebo. then ECG is taken every 30 minutes by Heart Rate Variability recording device and eProbe software for 4 hours. Two weeks later every 30 participants are given a second pack and the ECG is taken again.

Participants/Inclusion and exclusion criteria

Healthy young individuals between 19 to 26 years old with normal Body Mass Index

Intervention groups

At the beginning of the intervention, each participant will be given a pack with a three-digit code that contains Ginger 250 mg capsule or placebo, then every 30 minutes for 4 hours, ECG is taken using HRV recorder and eProbe software. Two weeks later, the second pack will be given and the ECG will be taken every half an hour for 4 hours. The data will be analyzed using Prism statistical software version SPSS 25 And thus, the effect of Ginger 250 mg capsule on the frequency domain heart rate variability measures can be evaluated.

Main outcome variables

Effect of Ginger 250 mg capsules on Heart Rate Variability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230701058637N1**

Registration date: **2023-08-03, 1402/05/12**

Registration timing: **prospective**

Last update: **2023-08-03, 1402/05/12**

Update count: **0**

Registration date

2023-08-03, 1402/05/12

Registrant information

Name

Iraj Jafaripour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3219 9592

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-05, 1402/05/14

Expected recruitment end date

2023-09-05, 1402/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of single dose administration of ginger on frequency domain heart rate variability measures in young healthy subjects

Public title

Effect of Ginger on Heart Rate Variability (HRV)

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy subjects Normal Body Mass Index (BMI) 19 to 26 years old

Exclusion criteria:

Smoking Alcohol consumption Substance abuse
Cardiovascular diseases Acute and chronic diseases
Prohibition of Ginger

Age

From **19 years** old to **26 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a table of random numbers, a three-digit code is inserted on each pack These packs are divided into two drug or placebo groups. None of the studied person and the researcher know about its type Each person will be given two packs with two identical capsules, each of which will be Ginger 250 mg or placebo. To randomize the above process, a 3-digit code will be written on each pack and this number will be included on each person's checklist. It is explained to the participants of the study that in the first week they will take the first pack of capsules and two weeks later, they will take the second pack of capsules .

Blinding (investigator's opinion)

Double blinded

Blinding description

Each person will be given two packs with two identical capsules, each of which will be Ginger 250 mg or placebo. None of the studied person and the researcher know about its type To randomize the above process, a 3-digit code will be written on each pack and this number will be included on each person's checklist. It is explained to the participants of the study that in the first week they will take the first pack of capsules and two weeks later, they will take the second pack of capsules .

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Keshavarz Boulevard

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Province

Mazandaran

Postal code

4717647745

Approval date

2023-07-25, 1402/05/03

Ethics committee reference number

IR.MUBABOL.REC.1402.045

Health conditions studied

1

Description of health condition studied

young healthy subjects

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of Ginger 250 mg capsules on HRV

Timepoint

Before starting the intervention and every 30 minutes after the start of taking Ginger 250 mg capsules or placebo for 4 hours

Method of measurement

HRV recording device and eprobe software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At the beginning of the intervention, each participant is given a pack with a three-digit code

that contains 250 mg Ginger capsules or placebo, then every half an hour, ECG will be taken using HRV recorder and ePobe software for 4 hours.

Category

N/A

2**Description**

Control group: Two weeks later a second pack with three-digit code that contains 250 mg Ginger capsule or placebo will be given to the same participants then every half an hour, ECG will be taken using HRV recorder and ePobe software for 4 hours

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rouhani Hospital

Full name of responsible person

Dr Iraj Jafaripour

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

Babol 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?**

Yes

Title of funding source

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Dr Iraj Jafaripour

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

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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