

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Assessment of Cardiac autonomic system responses to oral administration of Dimenhydrinate in healthy young subjects

Protocol summary

Study aim

Evaluation of cardiac autonomic nervous system response to oral consumption of Dimenhydrinate in healthy young volunteers.

Design

Double-blind clinical trial with crossover placebo control to evaluate cardiac autonomic nervous system response to oral Diaminehydrinate 50 mg in 15 healthy young volunteers. A table of random numbers is used for randomization

Settings and conduct

In Rouhani Hospital, at the beginning of the intervention, 15 healthy young subjects aged 19 to 26 years old with normal BMI are given a pack with a three-digit code that contains Dimenhydrinate 50 mg tablets or placebo. then ECG is taken every half an hour by HRV recording device and eprobe software for 4 hours. Two weeks later every 15 participants are given a second pack and the ECG is taken again.

Participants/Inclusion and exclusion criteria

Healthy young individuals aged 19 to 26 years old with normal BMI

Intervention groups

At the beginning of the intervention, each participant is given a pack with a three-digit code that contains 50 mg Dimenhydrinate tablets or placebo, then every half an hour, ECG is taken using HRV recorder and epobe software for 4 hours. Two weeks later, the second pack is given and the ECG is taken every half an hour for 4 hours. The data will be analyzed using Prism statistical software version spss229. And thus, the effect of Dimenhydrinate 50 mg tablets on the response of the cardiac autonomic nervous system can be evaluated.

Main outcome variables

The effect of Dimenhydrinate 50 mg tablets on HRV

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230606058390N1**

Registration date: **2023-07-01, 1402/04/10**

Registration timing: **prospective**

Last update: **2023-07-01, 1402/04/10**

Update count: **0**

Registration date

2023-07-01, 1402/04/10

Registrant information

Name

Roghayeh Pourkia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 9592

Email address

dr.pourkia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Cardiac autonomic system responses to oral administration of Dimenhydrinate in healthy young subjects

Public title

Effect of Dimenhydrinate on Heart Rate Variability (HRV)

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

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

Exclusion criteria:

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

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: **15**

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 pills, each of which will be Dimenhydrinate 50 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 pills and two weeks later, they will take the second pack of pills .

Blinding (investigator's opinion)

Double blinded

Blinding description

Each person will be given two packs with two identical pills, each of which will be Dimenhydrinate 50 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 pills and two weeks later, they will take the second pack of pills .

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 Science

Street address

Babol University of Medical Sciences, Keshavarz Boulevard

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2023-05-29, 1402/03/08

Ethics committee reference number

IR.MUBABOL.REC.1402.018

Health conditions studied**1****Description of health condition studied**

Assessment of Cardiac autonomic system responses to oral administration of Dimenhydrinate in healthy subjects

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The effect of Dimenhydrinate 50 mg tablets on HRV

Timepoint

Before starting the intervention and every 30 minutes after the start of taking Dimenhydrinate tablets 50 mg or placebo for 4 hours.

Method of measurement

HRV recording device and eprobe software

Secondary outcomes

empty

Intervention groups**1****Description**

At the beginning of the intervention, each participant is given a pack with a three-digit code that contains 50 mg Dimenhydrinate tablets or placebo, then every half an hour, ECG is taken using HRV recorder and eprobe

software for 4 hours. Two weeks later, the second pack is given and the ECG is taken every half an hour for 4 hours

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouhani Hospital

Full name of responsible person

Dr Roghayeh Pourkia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

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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 Roghayeh Pourkia

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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

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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