

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Cardiac autonomic system responses to oral administration of Hydroxyzine hydrochloride in male healthy subjects.

Protocol summary

Summary

Hydroxyzine is a first-generation antihistamine of the diphenylmethane and piperazine class. Due to its antagonistic effects on several receptor systems in the brain, hydroxyzine is claimed to have strong anxiolytic and mild antiobsessive as well as antipsychotic properties. Studies of heart rate variability (HRV) present a noninvasive, simple, and quantitative tool of evaluating autonomic performance on the heart. In this study, we intend to assess the effects of acute oral Hydroxyzine on heart rate variability (HRV). The Hydroxyzine (doses of 5, 10 and 20 mg) or placebo administer in four different testing sessions. The 15 healthy subjects would included in the study. In ever session, power spectral analysis of HRV parameters will assess in the supine position before and after the participants were given placebo or different doses of Hydroxyzine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051611236N5**

Registration date: **2014-05-26, 1393/03/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-26, 1393/03/05

Registrant information

Name

Esmail Akbari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy for Research, Mazandaran University of Medical Sciences

Expected recruitment start date

2014-05-20, 1393/02/30

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cardiac autonomic system responses to oral administration of Hydroxyzine hydrochloride in male healthy subjects.

Public title

Effect of oral Hydroxyzine on heart rate variability

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: male; ages between 19-24 years old.

Exclusion criteria: chronic disease (i.e. diabetes mellitus, hypertension, epilepsy and etc); smoker; under regular medication .

Age

From **19 years** old to **24 years** old

Gender

Male

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mazandaran University of Medical Sciences

Street address
Deputy for Research, Moalem Square, Buil. No 2,
Mazandaran University of Medical Sciences, Sari, Iran.

City
Sari

Postal code

Approval date
2013-11-23, 1392/09/02

Ethics committee reference number
91198

Health conditions studied

1

Description of health condition studied
Healthy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
mean of RR interval

Timepoint
before and after administration of placebo or drug

Method of measurement
Time domain analysis of ECG

Secondary outcomes

1

Description
Standard deviation of RR interval

Timepoint
before and after administration of placebo or drug

Method of measurement
Time domain analysis of ECG

2

Description
High frequency power spectrum

Timepoint
before and after administration of placebo or drug

Method of measurement
Frequency domain analysis of ECG

Intervention groups

1

Description
Oral administration of 10 mg Hydroxyzine

Category
Treatment - Drugs

2

Description
Oral administration of 5 mg Hydroxyzine

Category
Treatment - Drugs

3

Description
Oral administration of placebo.

Category
Placebo

4

Description
Oral administration of 20 mg Hydroxyzine

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Medical Sciences of mazandaran University

Full name of responsible person

Street address

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy for Research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad-ali Enayati

Street address

Deputy for Research, Moalem Square, Buil. No 2,
Mazandaran University of Medical Sciences, Sari, Iran.
Sari Mazandaran

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy for Research, Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Physiology, School of Medicine,
Mazandaran University of Medical Sciences, Sari

Full name of responsible person

Esmaeil Akbari

Position

Ph.D

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty