

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of body posture (standing, sitting, supine and squatting) on heart rate to valsalva maneuver in male healthy subjects.

Protocol summary

Summary

Valsalva maneuver is naturally done during behaviors such as coughing, heavy lifting, urinary excretion, and defecation. Despite the fact that both the body position and the valsalva maneuver may affect the cardiovascular autonomic system activity, so far, few studies were conducted about the effect of body position on heart rate responses to the valsalva maneuver. The aim of this study is to assess heart rate response to the valsalva maneuver in the standing, sitting, lying, and squatting postures in healthy young males. The design of this study determines that each subject (of the total subjects n=19) has to position in each of the four postures with a ten minute interval. Meanwhile standard valsalva maneuver, ECG lead II continuously is recorded for five min. Then, time and frequency domains of heart rate variability criteria are calculated. The inclusion criteria are being male and age of 19 to 24 and the exclusion criteria are chronic diseases (such as diabetes, hypertension, epilepsy, etc.), smokers, and chronic medication consumers. The interventions of the study include sitting, standing, and squatting positions in comparison with supine position. The mean and standard deviation of sequential R-R intervals are the primary outcomes of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040111236N7**

Registration date: **2016-11-15, 1395/08/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-11-15, 1395/08/25

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy for Research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-12-10, 1395/09/20

Expected recruitment end date

2017-01-10, 1395/10/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of body posture (standing, sitting, supine and squatting) on heart rate to valsalva maneuver in male healthy subjects.

Public title

The effect of body posture on heart rate response to valsalva maneuver.

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria: male; age 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)

Not blinded

Blinding description

Placebo

Not 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

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

City

Sari

Postal code

Approval date

2014-03-05, 1392/12/14

Ethics committee reference number

92482

Health conditions studied

1

Description of health condition studied

Healthy subjects

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean of RR interval

Timepoint

Five minutes during of supine or other position

Method of measurement

Time domain analysis of ECG

2

Description

Standard deviation of RR interval

Timepoint

Five minutes during of supine or other position

Method of measurement

Time domain analysis of ECG

Secondary outcomes

1

Description

High frequency power spectrum

Timepoint

Five minutes during of supine or other position

Method of measurement

Frequency domain analysis of ECG

2

Description

Low frequency power spectrum

Timepoint

Five minutes during of supine or other position

Method of measurement

Frequency domain analysis of ECG

Intervention groups

1

Description

Supine position

Category

Behavior

2

Description

Sitting position

Category

Behavior

3

Description

Squatting position

Category

Behavior

4

Description

Standing position

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Medicine, Mazandaran University of Medical Sciences

Full name of responsible person

Esmail Akbari

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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

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

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

Name of organization / entity

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

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Position

Associate Professor

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty