

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effect of variation in ambient temperature on vital signs and cardiac indices in echocardiography among healthy volunteer adults: a before-after clinical trial

Protocol summary

Study aim

To assess the effect of variation in ambient temperature on vital signs and cardiac indices in echocardiography among healthy volunteer adults: a before-after clinical trial

Design

This is a before-after clinical trial, in which 20 eligible healthy volunteer adults will be enrolled

Settings and conduct

The eligible healthy volunteer adults will be invited to the Besat Hospital in Hamadan City

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 55 years Healthy adults class ASA one and two Exclusion criteria: Presence of any chronic or background disease

Intervention groups

Intervention group: The ambient temperature from the base of 23 °C every two degrees for two minutes to a maximum of 39 °C

Main outcome variables

Measuring systolic and diastolic blood pressure
Measuring arterial blood pressure
Measuring the number of breathing
Measuring heart rate
Measuring the changes in the walls of the heart cavity
Measuring central and tympanic
Measuring consciousness level
Measuring arterial oxygen percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N274**
Registration date: **2019-05-11, 1398/02/21**
Registration timing: **prospective**

Last update: **2019-05-11, 1398/02/21**

Update count: **0**

Registration date

2019-05-11, 1398/02/21

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of variation in ambient temperature on vital signs and cardiac indices in echocardiography among healthy volunteer adults: a before-after clinical trial

Public title

Effect of variation in ambient temperature on vital signs and cardiac indices in echocardiography among healthy

volunteer adults

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 55 years Healthy adults class ASA one and two

Exclusion criteria:

Presence of any chronic or background disease

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-05-04, 1398/02/14

Ethics committee reference number

IR.UMSHA.REC.1398.082

Health conditions studied

1

Description of health condition studied

Healthy volunteer adults

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Measuring systolic and diastolic blood pressure

Timepoint

At supine position 2 minutes after intervention

Method of measurement

With a monitor device

2

Description

Measuring arterial blood pressure

Timepoint

At supine position 2 minutes after intervention

Method of measurement

With a monitor device

3

Description

Measuring the number of breathing

Timepoint

At supine position 2 minutes after intervention

Method of measurement

With a monitor device

4

Description

Measuring heart rate at supine position 2 minutes after intervention

Timepoint

At supine position 2 minutes after intervention

Method of measurement

With a monitor device

5

Description

Measuring the changes in the walls of the heart cavity

Timepoint

At supine position 2 minutes after intervention

Method of measurement

With echocardiography

6

Description

Measuring central and tympanic

Timepoint

At supine position 2 minutes after intervention

Method of measurement

With a monitor device

7

Description

Measuring consciousness level

Timepoint

At supine position 2 minutes after intervention

Method of measurement

With a clinical examination and GCS

8

Description

Measuring arterial oxygen percentage

Timepoint

At supine position 2 minutes after intervention

Method of measurement

With a monitor device

9

Description

Measurement of strike volume

Timepoint

At supine position 2 minutes after intervention

Method of measurement

With echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The ambient temperature from the base of 23 °C every two degrees for two minutes to a maximum of 39 °C

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan City

Full name of responsible person

Dr Abbas Taher

Street address

Besat Hospital, Shahed Square

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3364 0030

Email

t_anesthesia@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Abbas Taher

Position

Anesthesiologist

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Besat Hospital, Shahed Square

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3364 0030

Email

t_anesthesia@yahoo.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Abbas Taher

Position

Anesthesiologist

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Other areas of specialty/work

Anesthesiology

Street address

Besat Hospital, Shahed Square

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Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3364 0030

Email

t_anesthesia@yahoo.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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