

# 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

**Latest degree**

Medical doctor

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6517838695

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**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

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**Province**

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**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