

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparison of the effect of Valsalva maneuver and auricular acupressure on pain intensity of peripheral venous cannulation

#### Protocol summary

##### Study aim

Comparison of Valsalva maneuver and auricular acupressure on pain intensity of peripheral venous cannulation

##### Design

The present study is a three-arm, parallel-group randomized clinical trial

##### Settings and conduct

The present study is a three-arm randomized clinical trial with parallel groups on 105 patients. Sampling will be available. Then, the eligible patients were randomly assigned by permuted block randomization in the form of triple blocks (ABC, ACB, BAC, BCA, CAB, CBA) in each of the three groups of Valsalva maneuver, acupressure (auriculotherapy) and are placed under routine care.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients over 18 years of age, who are placed at levels 5 and 4 of hospital triage - Require for cannulation - Having a vein in the antecubital area of the forearm - Not having a history of heart disease according to self-report - Not having acute pain - No Trauma - Willingness to participate in the study - Consciousness level 15 - Not being addicted to drugs - Not taking sedatives and tranquilizers in the last six hours Exclusion criteria: -Patients who experience a decreased consciousness level during the study -Failure to cannulation in the first attempt.

##### Intervention groups

In the Valsalva maneuver group, patients exhale for twenty seconds with a closed glottis, and then peripheral cannulation is performed by the researcher. In the auricular acupressure group, patients are stimulated by the researcher for two minutes from the ear area and then peripheral cannulation is performed by the researcher. In the control group, the routine intervention of the ward, i.e. closing the tourniquet and then inserting the cannulation of the peripheral vein, is performed.

##### Main outcome variables

Pain intensity of peripheral venous cannulation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240106060628N1**

Registration date: **2024-02-16, 1402/11/27**

Registration timing: **prospective**

Last update: **2024-02-16, 1402/11/27**

Update count: **0**

##### Registration date

2024-02-16, 1402/11/27

##### Registrant information

##### Name

Sayyed Reza Hoseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 3642 3594

##### Email address

www.hoseinirz9@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-19, 1402/11/30

##### Expected recruitment end date

2024-04-19, 1403/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of Valsalva maneuver and auricular acupressure on pain intensity of peripheral venous cannulation

#### Public title

Comparing of Valsalva maneuver and acupressure on pain of peripheral cannulation

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

- Patients over 18 years of age who are placed at level 5 and 4 of hospital triage - Require for peripheral venous cannulation - Access to the vein in the antecubital area of the forearm - Not having a history of heart disease - Not having acute pain - No trauma - Willingness to participate in the study - Consciousness level of 15 based on Glasgow coma scale - Not addiction - Not taking sedatives and tranquilizers in the last six hours

##### Exclusion criteria:

Patients who have a decreased level of consciousness during the study Failure to cannulation in the first attempt

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **96**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random allocation will be by permutation blocks. Eligible patients, based on random allocation by permuted block randomization in the form of three blocks (ABC, ACB, BAC, BCA, CAB, CBA) in each of the three groups of Valsalva maneuver, acupressure (auriculotherapy), and routine care, will be placed. Concealment of the random allocation is also done using the method of sealed envelopes. In this method, the allocation sequence is placed inside the numbered envelopes, and the eligible patients are placed in each of the three groups based on the specified envelope to reduce selection bias.

#### 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

Ethics committee of Gonabad University of Medical Sciences

##### Street address

Vice Chancellor of Education, Research and Student Culture of Gonabad University of Medical Sciences - Razavi Khorasan Province-Gonabad-side of the Asian road

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

#### Approval date

2024-01-22, 1402/11/02

#### Ethics committee reference number

IR.GMU.REC.1402.145

## Health conditions studied

### 1

#### Description of health condition studied

Hypertensive heart disease

#### ICD-10 code

I11

#### ICD-10 code description

Hypertensive heart disease

### 2

#### Description of health condition studied

Abnormalities of breathing

#### ICD-10 code

R06

#### ICD-10 code description

Abnormalities of breathing

### 3

#### Description of health condition studied

Nausea and vomiting

#### ICD-10 code

R11

#### ICD-10 code description

Nausea and vomiting

## Primary outcomes

### 1

#### Description

Peripheral vein cannulation pain intensity based on Visual analogue scale

#### Timepoint

Immediately after peripheral vein cannulation

## Method of measurement

Pain assessment scale including Visual analogue scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In auricular acupressure group, patients are stimulated by the researcher for two minutes from the ear area and then peripheral cannulation is performed by the researcher.

#### Category

Other

### 2

#### Description

In the Valsalva maneuver group, patients exhale for twenty seconds with a closed glottis, and then peripheral cannulation is performed by the researcher.

#### Category

Other

### 3

#### Description

In the control group, the routine intervention of the ward, i.e. closing the tourniquet and then inserting the cannulation of the peripheral vein, is performed.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razavi Khorasan Province, Gonabad City, Saadi St., Nurse Boulevard, Allameh Bahloul Gonabadi Hospita

##### Full name of responsible person

Seyed Reza Hosseini

##### Street address

Allameh Bahloul Gonabadi Hospital, Saadi St., Nurse Boulevard, Gonabad City, Razavi Khorasan Province.

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691699967

##### Phone

+98 51 5723 6832

##### Fax

+98 51 5723 6160

##### Email

Bohloulipd@gmu.ac.ir

## Web page address

<https://bohloul.gmu.ac.ir/index.html>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

Leila Sadeghi Moghadam

##### Street address

Research and Technology Vice-Chancellor of Gonabad University of Medical Sciences, near the Asian road, Gonabad, Khorasan Razavi

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691699967

##### Phone

+98 51 5722 3028

##### Fax

+98 51 5722 0578

##### Email

Bohloulipd@gmu.ac.ir

##### Web page address

<https://bohloul.gmu.ac.ir/index.html>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Gonabad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Seyed Reza Hosseini

##### Position

Master of Sciences in Nursing (MSC) student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

**Street address**

No. 39, 15 Qaim St., Mashhad, Razavi Khorasan.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9188757879

**Phone**

+98 51 3657 3015

**Email**

www.hoseinirz941@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyed Reza Hosseini

**Position**

collegian

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 39, 15 Qaim Street, Mashhad City, Razavi Khorasan Province.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9188757879

**Phone**

+98 51 3657 3015

**Email**

www.hoseinirz941@gmial.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyed Reza Hosseini

**Position**

collegian

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 39, 15 Qaim Street, Mashhad City, Razavi

Khorasan Province.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9188757879

**Phone**

+98 51 3657 3015

**Email**

www.hoseinirz941@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

After the completion of the study, in addition to the report of the end of the project in the Pajoochan system, the article is published in English or Farsi, in which detailed information is provided about the method and data analysis. If more information is needed by the researchers, they can contact the authors of the study through email so that appropriate information is provided to them if necessary.

**When the data will become available and for how long**

Access will be available after the publication of the article.

**To whom data/document is available**

All those whom the data of the present study will help to disseminate scientific knowledge can send their request.

**Under which criteria data/document could be used**

The use of data must: - To promote science. - Consider ethical issues - Cite to the current article.

**From where data/document is obtainable**

They can send their request through the email listed following: hoseinirz941@gmail.com

**What processes are involved for a request to access data/document**

Immediately after the email request, they will be provided with the review request and the required data that does not cause any problems from an ethical point of view.

**Comments**