

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Leila Sadeghi Moghadam

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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

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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