Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Sayyed Reza Hoseini
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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
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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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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 Pajoohan 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