Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of distraction technique and valsalva maneuver on the intensity of peripheral venous cannulation pain in patients refer to the Emergency department of Imam Khomeini hospital in Esfarayne city in year 2019

Protocol summary

Study aim
Comparison of the effect of distraction technique and valsalva maneuver on the intensity of peripheral venous cannulation pain

Design
A clinical trial with a control group, with crossover groups, a blind, randomized, randomized, one-way clinical trial The sample size of 150 people was initially performed as an easy sampling and then randomized in the intraperitoneal venous catheter placement with the Phase II trial.

Settings and conduct
This is a clinical trial performed on individuals aged 18-60 years old referred to the emergency department of Imam Khomeini Hospital in Esfarayn, Iran. The criteria for entering the study include the need for intravenous venous catheterization. Angiocate 20 is used for placement, and both angiocate insertion and replacement are performed simultaneously from the same site on both hands. The time for the replacement of the angiocate is also carefully recorded. A single-blind study was conducted that only statistical analysis of the type of intervention in each group was not known.

Participants/Inclusion and exclusion criteria
People aged 18-60 years old where criteria for entering the study, including the need for intravenous route, are included in the study. Patient with heart disease, hemodialysis, patient with skin and vascular disorders, signs of lowering sensation and movement in the upper limb under peripheral venous vein are not included.

Intervention groups
In the first and second intervention group, both interventions: Valdasva's deviant technique and maneuver are cross-over and the results are evaluated by an VAS. There was no intervention in the control group and only the pain intensity of the patients angiocate insertion was evaluated.

Main outcome variables
Determine a convenient and affordable method with easy access and easy learning to reduce the pain of insertion of peripheral venous catheter in patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190428043408N1**
Registration date: **2019-05-07, 1398/02/17**
Registration timing: **prospective**

Last update: **2019-05-07, 1398/02/17**
Update count: **0**

Registration date
2019-05-07, 1398/02/17

Registrant information

Name
Javad Sedaghati

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-21, 1398/02/31

Expected recruitment end date
2019-06-21, 1398/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of distraction technique and valsalva maneuver on the intensity of peripheral venous cannulation pain in patients refer to the Emergency department of Imam Khomeini hospital in Esfarayne city in year 2019

Public title
Comparison of the effect of distraction technique and valsalva maneuver on the intensity of peripheral venous cannulation pain
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
A patient aged 18-60 The patient needs to be admitted to the hospital and have an intravenous line with an intravenous venous catheter The patient is aware of the time, place and person Possibility of placement of angioquate number 20 in the patient
Exclusion criteria:
The patient has a history of heart disease The patient becomes hemodialysis The patient has skin and vascular disorders (erythema, itching, bruising, etc.) at the site The patient has symptoms of lowering the sensation and movement of the upper limb under intravenous venipuncture The patient has a pain associated with the disease The patient has a narcotic use before and after prolonged use, and is within the range of the duration of the effect of these drugs The patient has an abnormal level of consciousness For any reason, the patient needs to have any angioquate with no number 20
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization method and individual randomization unit. Individuals are randomly assigned to one of the three study groups with the help of a random number table and receive the intervention of the same group.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, according to the conditions for intervention in the patients, the obstetrician nurse and the pain monitoring nurse, a single-blind study was conducted that only statistical analysis of the type of intervention in each group was not known.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
Street address
Tohid Shahr Blvd. (Nuclear Martyrs), above the Mazar Martyrs of Anonymous, Campus Complex, Sabzevar University of Medical Sciences. Postcode: 9617213112
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617213112
Approval date
2019-04-27, 1398/02/07
Ethics committee reference number
IR.MEDSAB.REC.1398.007

Health conditions studied

1

Description of health condition studied
Pain for peripheral venous angiocate in patients who have entered the study. Such as internal, surgical and ...
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Score of angiocate pain in the questionnaire VAS
Timepoint
Measurement of angiocate insertion pain during venous catheterization during the study
Method of measurement
VAS pain questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In the first incision with angiocate in the patient, the deviation technique was used to squeeze a flexible rubber toper in the opposite hand, and in the second time the same patient, the Valsalva maneuver was used as a compression expander with a concurrent gluteus By taking and pressing the tip of the nose.
Category
Prevention

2

Description
Second intervention group: In the first time with angiocate, the Valsalva maneuver was performed as an expiratory compression with a closed glottis as the nose tip was taken and pushed, and at the second time, the patient was deformed, the deviation of thought by squeezing a rubber toper. Flexibility is done in the opposite direction.
Category
Prevention

3

Description
Control group: The placement of an angiocate of the peritoneal vein is carried out without additional work.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emergency department of Imam Khomeini hospital in Esfarayne city
Full name of responsible person
Javad Sedaghat: student , Hassan Khalili: Supervisor
Street address
Esfarayen, Taleghani St., Central Building, Esfarayne School of Medical Sciences. Zip code: 76981-96618
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mostafa Rad
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Javad Sedaghati
Position
Nursing Graduate Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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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