

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

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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