

# 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

+98 58 3722 2871

##### Email address

sedaghatij96@medsab.ac.ir

##### 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

##### City

Esfarayne

##### Province

North Khorasan

##### Postal code

76981-96618

##### Phone

+98 58 3722 6004

##### Email

Info@esfrums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mostafa Rad

##### Street address

Tohid Shahr Blvd. (Nuclear Martyrs), above the Mazar Martyrs of Anonymous, Campus Complex, Sabzevar University of Medical Sciences. Postcode: 9617213112

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##### Phone

+98 51 4401 8300

##### Email

info@medsab.ac.ir

##### 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

##### Street address

No.45, TALEGHANI STREET 7

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##### Province

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Position**

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**Latest degree**

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**Latest degree**

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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