

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of closing two tourniquets versus closing one tourniquet on the success of access to a peripheral venous line in emergency department patients

Protocol summary

Study aim

Comparison of the success rate of closing two tourniquets and one tourniquet in peripheral venous line access in patients of the emergency department of Vasi Hospital in Sabzevar city.

Design

Clinical trial with a control group, with parallel groups, double-blind, There is not blinding, phase 3 on 100 patients, randomization load using permutation blocks

Settings and conduct

After the approval of the project and obtaining the code of ethics and IRCT, we referred to the emergency department of Vasei Hospital in Sabzevar and selected the patients who referred to the emergency department and met the study inclusion criteria using the convenience method. The written informed consent of patients was obtained. Then, the patient's demographic information questionnaire and clinical trial application checklist were completed.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. The need to establish a venous line, 2. Having consent to participate in the study, 3. The age of the studied patients is limited to 20-50 years 4. Pregnancy (other than absence, patients are considered high risk group) Exclusion criteria: having a life-threatening condition (emergency), edema, obesity, peripheral vascular disease, Raynaud's phenomenon, scleroderma, sickle cell anemia, methemoglobinemia, patients with a history of any drug allergy and underlying diseases, including cardiovascular, high blood pressure, coagulation disorder, excessive bleeding, Hb less than 10, kidney failure, drug abuse and skin infection, and patients are less than 20 years old and more than 50 years old.

Intervention groups

Intervention group: 50 patients with two tourniquets
Control group: 50 patients with a tourniquet

Main outcome variables

success in accessing the peripheral venous line

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220713055459N1**

Registration date: **2023-04-06, 1402/01/17**

Registration timing: **prospective**

Last update: **2023-04-06, 1402/01/17**

Update count: **0**

Registration date

2023-04-06, 1402/01/17

Registrant information

Name

Vahid Deldar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5456 3515

Email address

vahiddeldar1375@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-19, 1402/01/30

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of closing two tourniquets versus closing one tourniquet on the success of access to a peripheral venous line in emergency department patients

Public title
The effect of closing one and two tourniquets on the success of peripheral venous access

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The need to establish a venous line Consent to participate in the study The age of the studied patients is limited to 20-50 years Pregnancy (other than absence, patients are considered high risk group) Consciousness of the patient
Exclusion criteria:
Having a life-threatening condition (emergency) Edema Excessive obesity Peripheral vascular disease Raynaud's phenomenon Scleroderma Sickle cell anemia methemoglobinemia Patients with a history of any drug allergy and underlying disease, including cardiovascular Hypertension Coagulation disorder Hemoglobin less than 10 Renal failure Drug abuse skin infection Age limit (at least 20 years old and more than 50 years old)

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the permuted block technique, the patients were divided into two groups of one tourniquet and two tourniquets. In this way, each block of n=4 was allocated to the intervention group of n=2 and the control group of n=2. A total of six blocks in different states were obtained and each block was numbered with a number. The blocks of n=4 were selected based on the table of random numbers until the sample size reached n=100. Finally, 50 patients were in the control group and 50 patients were in the intervention group. This was repeated until the end of sampling. In allocation concealment technique, the participants themselves were not aware of the type of educational intervention and the data analyst was not aware of the group due to the coding of the data. To avoid bias, sampling was done by an officially employed male nurse with at least two years of clinical work experience.

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 Sabzevar University of Medical Sciences
Street address
Sabzevar Univercity Of Medical Sciences,Asad Abadi Ave
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Approval date
2022-07-12, 1401/04/21
Ethics committee reference number
IR.MEDSAB.REC.1401.021

Health conditions studied

1

Description of health condition studied
Double Tourniquetes Technique
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Success in peripheral venous line access
Timepoint
Immediately
Method of measurement
Clinical results registration checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Using double tourniquets to access the peripheral venous lines

Category

Treatment - Devices

2

Description

Control group: Using single tourniquets to access the peripheral venous lines

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei Hospital

Full name of responsible person

Vahid Deldar

Street address

Vasei Hospital,Asadabadi Ave,Sabzevar Town

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Email

waseehospital@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

MohammadHosein Saghi

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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

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

Vahid Deldar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Abdolghader Assarroudi

Position

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the confidentiality of the information, it will be sent to them confidentially if requested by the journal or the reviewers of the journal or other competent legal authorities.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Due to the confidentiality of the information, it will be sent to them confidentially if requested by the journal or the reviewers of the journal or other competent legal authorities.

When the data will become available and for how long

2023-2026

To whom data/document is available

Scientific institutions and people working in scientific and academic institutions

Under which criteria data/document could be used

Use of study results - perform secondary analysis

From where data/document is obtainable

ghaderassar@yahoo.com

What processes are involved for a request to access data/document

Send an email to the study supervisor

Comments