

# 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

#### City

Sabzevar

#### Province

Razavi Khorasan

#### Postal code

9617747431

#### Phone

+98 51 4465 1300

#### 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

#### Street address

Sabzevar University Of Medical Sciences,Asad Abadi Ave

#### City

Sabzevar

#### Province

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#### Postal code

9617913114

#### Phone

+98 51 4401 1000

#### Email

info@medsab.ac.ir

#### Web page address

<https://www.medsab.ac.ir/>

### 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

#### Street address

ImamReza Blvd

#### City

Taybad

#### Province

Razavi Khorasan

#### Postal code

9593119187

#### Phone

009854563515

#### Email

vahiddeldar1375@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Sabzevar University of Medical Sciences

#### Full name of responsible person

Abdolghader Assarroudi

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

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Asad Abadi Ave

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ghaderassar@yahoo.com

**Web page address**

[http://isid.research.ac.ir/Abdolghader\\_Assarroudi](http://isid.research.ac.ir/Abdolghader_Assarroudi)

**Person responsible for updating data**

**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

**Street address**

ImamReza Blvd

**City**

Taybad

**Province**

Razavi Khorasan

**Postal code**

9593119187

**Phone**

009854563515

**Email**

vahiddeldar1375@gmail.com

**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**