

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparison of two methods of local heat and massage on outcomes of venipuncture in hospitalized children: A randomized controlled clinical trial

#### Protocol summary

##### Study aim

Comparison of local heat and massage on the results of venipuncture

##### Design

A clinical trial with a control group, with parallel groups, one-way blinded, with three and six random blocks, on 96 patients, randomized by using the Rand List function.

##### Settings and conduct

Vein extraction will be performed on selected children in the operating room of Mardani Children's Hospital in Azar-Tabriz, after the intervention by two expert nurses. Vein evaluation will be done using the vein evaluation scale before the intervention and the score will be recorded. The time taken to access the intravenous line will be recorded in seconds using a stopwatch. The child's pain score will be determined using the VAS scale, before and immediately after the venipuncture. Blinding will be done only in the data analysis phase of the study (statistical consultant).

##### Participants/Inclusion and exclusion criteria

Entry criteria: Hospitalized children aged 6-12 Indication of peripheral catheter insertion Difficult venous access score (DIVA)  $\geq 4$  Do not prescribe painkillers 4 hours before inserting the catheter Ability to communicate verbally Non-entry criteria: Skin sensitivity or the presence of wounds, eczema at the site Presence of cognitive impairment Apathy or uncooperativeness

##### Intervention groups

Local heat group: The thermal pad will be placed on the selected vein for 5 minutes up to  $40 \pm 2$  degrees Celsius. Then the cannulation will be done by the researchers. massage group: forearm skin massage will be applied using fingertips with slow circular movements, from the wrist to the cubital cavity for at least 2 minutes without interruption. Then the cannulation is done by the researcher. control group: venous cannulation will be performed.

##### Main outcome variables

Pain intensity during venous cannulation using the Visual Analog Scale. Investigating the time of successful venous cannulation using a stopwatch

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230722058885N1**

Registration date: **2023-11-24, 1402/09/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-11-24, 1402/09/03**

Update count: **0**

##### Registration date

2023-11-24, 1402/09/03

##### Registrant information

##### Name

samieh naseri nahr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3385 0598

##### Email address

naserinahr@tbzmed.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2023-10-22, 1402/07/30

##### Expected recruitment end date

2023-12-21, 1402/09/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of two methods of local heat and massage on outcomes of venipuncture in hospitalized children: A randomized controlled clinical trial

**Public title**  
" Effect of local heat on venipuncture in children"; " effect of massage on venipuncture in children"

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Children aged 6 to 12 admitted to one of the internal or surgical departments of the hospital Indication of peripheral vein catheter insertion Having a Difficult Venous Access (DIVA) score  $\geq 4$  Not prescribing painkillers or anesthetics 4 hours before inserting the IV catheter Absence of bleeding disorders The ability to communicate verbally  
**Exclusion criteria:**  
Skin sensitivity or the presence of wounds, eczema and skin rashes in the area The presence of cognitive impairment in the child Child's malaise or non-cooperation

**Age**  
From **6 years** old to **12 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Data analyser

**Sample size**  
Target sample size: **96**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Sampling will be done by the available method and using the Rand List program and random block method of three and six will be assigned to three groups of control, intervention 1 and intervention 2. In order to hide the assignment of children to three groups, opaque and sealed envelopes will be used, in such a way that the type of group is written on a sheet of paper and numbered inside the opaque envelopes. The envelopes will be opened by a person not involved in the study (department secretary) in the order of children's entry into the study, and the relevant group will be determined. Verbal information about the goals and how to conduct the study will be provided by the researcher to the children and their parents.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Due to the nature of the conducted interventions, it is

not possible to blind the researcher, help of researchers and samples, and blinding will be done only in the data analysis phase of the study (statistical consultant).

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical sciences

##### Street address

No.20,second Shaghayegh ave,Ferdows street,Elgholi,Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167954416

#### Approval date

2023-10-16, 1402/07/24

#### Ethics committee reference number

IR.TBZMED.REC.1402.546

## Health conditions studied

### 1

#### Description of health condition studied

Comparison of the effect of local heat and massage on pain and duration of venipuncture in hospitalized children

#### ICD-10 code

XXI

#### ICD-10 code description

Persons encountering health services for examination and investigation(Z00-Z13)

## Primary outcomes

### 1

#### Description

Duration of vein cannulation

#### Timepoint

By placing the cannula in the vein, the time interval from the moment the needle enters the skin until the needle exits and guiding the cannula to the end in the vein

#### Method of measurement

Using a stopwatch

## 2

### Description

Pain during intravenous cannulation

### Timepoint

Immediately after cannulation of venipuncture

### Method of measurement

Visual Analog Scale

## Secondary outcomes

### 1

#### Description

Evaluation of visibility and palpability of peripheral veins

#### Timepoint

Before and after intervention (local heat and massage)

#### Method of measurement

Vein Assessment Scale

## Intervention groups

### 1

#### Description

Intervention group1: The first intervention group: local heat with a heating pad, for 5 minutes, between 38-42 degrees Celsius.

#### Category

Other

### 2

#### Description

Intervention group2: Skin massage for two minutes

#### Category

Other

### 3

#### Description

Control group: Non-interventional venipuncture

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mardani Azar Tabriz Children's Hospital

##### Full name of responsible person

Samieh Naseri Nahr

##### Street address

No 20, Shaghayegh ave, Ferdous street, El Goli, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167954416

##### Phone

+98 936 996 0451

##### Email

samiehn@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Parviz Shahabi

##### Street address

No 20, Shaghayegh ave, Ferdous street, El Goli, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167954416

##### Phone

+98 936 996 0451

##### Email

samiehn@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Samieh Naseri Nahr

##### Position

Student

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

No 20, Shaghayegh ave, Ferdous street, El Goli,

Tabriz  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5167954416  
**Phone**  
+98 936 996 0451  
**Email**  
samiehnn@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Samieh Naseri Nahr  
**Position**  
Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
No 20, Shaghayegh ave, Ferdous street, El Goli,  
Tabriz  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5167954416  
**Phone**  
+98 936 996 0451  
**Email**  
samiehnn@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences

**Full name of responsible person**  
Samieh Naseri Nahr  
**Position**  
Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
No 20, Shaghayegh ave, Ferdous street, El Goli,  
Tabriz  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5167954416  
**Phone**  
+98 936 996 0451  
**Email**  
samiehnn@gmail.com

## 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