

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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) ≥ 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 ± 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 ≥ 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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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

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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