Clinical Trial Protocol
Iranian Registry of Clinical Trials

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