Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation of the Effect of Multisensory Tourniquet and Illustrated Tourniquet on Pain and Fear Associated with Intravenous Cannulation in Children Presenting to the Emergency Department

Protocol summary

Study aim

"Determining the Effect of Garoo Multisensory vs. Garoo Visual on Pain and Fear Associated with Venous Access in Children Aged 1 to 3 Years"

Design

This study is a randomized, two-group clinical trial conducted on 42 patients. The Random Allocation Software was used for randomization.

Settings and conduct

This study was conducted in the emergency department of Akbar Children’s Hospital, Mashhad. In the intervention group, a multisensory tourniquet (a butterfly-shaped toy with vibration, lights, and children's music) was applied 5–10 cm above the IV site, without pressure, for 5 minutes in the presence of a parent. Vibration was activated in the final minute. The child then entered the IV room, the tourniquet was tightened, and cannulation was performed. In the control group, a standard illustrated tourniquet was used, first loosely applied and then tightened before cannulation. Pain was assessed by a nurse blinded to group allocation. The data analyst was also blinded.

Participants/Inclusion and exclusion criteria

Inclusion critera:The child’s first injection experience during this admission. Exclusion criteria:If, after venous access is established, the insertion of the angiocatheter into the vein takes longer than 20 seconds.

Intervention groups

Intervention: A sensory tourniquet is applied 5 to 10 centimeters above the venipuncture site and will be released after the vein is located. Control group: A sensory tourniquet is applied 5 to 10 centimeters above the venipuncture site and will be released after the vein is located.

Main outcome variables

pain; fear

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250611066177N1**
Registration date: **2025-07-22, 1404/04/31**
Registration timing: **prospective**

Last update: **2025-07-22, 1404/04/31**
Update count: **0**

Registration date

2025-07-22, 1404/04/31

Registrant information

Name

Zahra Mirabi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2025-10-23, 1404/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigation of the Effect of Multisensory Tourniquet and Illustrated Tourniquet on Pain and Fear Associated with Intravenous Cannulation in Children Presenting to the Emergency Department

Public title
Investigation of the Effect of Multisensory Tourniquet and Illustrated Tourniquet on Pain and Fear Associated with Intravenous Cannulation in Children

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 1 to 3 years The child needs to have an IV inserted At least one parent should be present during the blood draw. The injection site will be on the back of the hand or the inner crease of the elbow, and the area should be free of scars or skin issues Before the procedure, the child should be alert and should not have received any sedatives, tranquilizers, or narcotics.

Exclusion criteria:
Parental dissatisfaction with the research First injection not successful If it takes more than 20 seconds to insert the angiocat into the vein after establishing the intravenous access in the child’s hand.

Age
From **1 year** old to **3 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the unit of randomization was the individual, meaning that each participant was independently assigned to either the intervention or control group. To ensure balance in the number of participants in each group throughout the allocation process, block randomization with fixed block sizes of six was employed. A total of seven six-person blocks were considered for the entire sample. The random allocation sequence within each block was generated using the Random Allocation Software. The sequence of group assignments (e.g., AABABB or ABABBA) was created entirely at random by the software. To ensure allocation concealment and minimize selection bias, the randomization process and assignment of participants to groups were carried out by an independent individual who was not part of the research team and had no knowledge of the group identities or study objectives. This approach ensured that group allocation was performed without researcher influence and in a fully blinded manner.

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
Mashhad University of Medical Sciences

Street address
Razavi Khorasan, Mashhad, Azadi Square, East Gate of Ferdowsi University of Mashhad, University Campus, Shahid Dr. Kharazmi Educational Complex

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Approval date
2025-05-20, 1404/02/30

Ethics committee reference number
IR.MUMS.NURSE.REC.1404.032

Health conditions studied

1

Description of health condition studied
Investigation of the Effect of Multisensory Tourniquet and Illustrated Tourniquet on Pain and Fear Associated with Intravenous Cannulation in Children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fear of opening an IV line

Timepoint
After the intervention begins

Method of measurement
Using the CMFS (Child Medical Fear Scale) questionnaire

Secondary outcomes

1

Description
Pain caused by opening a venous pathway

Timepoint

Immediately after opening the venous pathway

Method of measurement

Using the FLACC behavioral response scale(Face, Legs, Activity, Cry, Consolability)

Intervention groups

1

Description

Intervention group: In the intervention group, a multi-sensory tourniquet shaped like a butterfly and approximately 10 centimeters in size, capable of producing vibrations at a frequency of 90-95 Hz, has been designed. Lights are embedded in the wings of this butterfly, and children's music will play. While the child is with the parents, the nurse performing the venipuncture will place this musical tourniquet on the child's arm before entering the procedure room, but will not tighten it. For 5 minutes, it will be applied approximately 5-10 centimeters above the injection site, and in the last minute, vibrations will be activated. Then, the child, accompanied by one of the parents, will enter the procedure room, the multi-sensory tourniquet will be tightened, and the venipuncture will be performed immediately on the same arm of the child.

Category

Other

2

Description

Control group: In the control group, a patterned tourniquet with butterfly shapes will be placed on the child's arm for 5 minutes at a distance of 5 to 10 centimeters above the venipuncture site before entering the procedure room (it should be noted that the tourniquet will not be tightened before the venipuncture process begins). After entering the procedure room, the tourniquet will be tightened and fixed, and after completing the venous pathway opening process, the patterned tourniquet will be removed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

zahramirabi

Position
student
Latest degree
Bachelor
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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
No - There is not 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
Not applicable