Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of virtual reality with a vibrator combined with cold on pain, anxiety, and fear caused by venipuncture children

Protocol summary

Study aim
Study and comparison of the effects of virtual reality and vibrator combined with cold on pain, fear, and anxiety caused by venipuncture in children referred to the pediatric emergency department of Hakim Hospital

Design
A controlled, parallel-group, single-blind, randomized clinical trial on 177 children. A permutational block design was used for randomization.

Settings and conduct
Study location: Pediatric emergency room of Hakim Hospital in Neyshabur; Study population: Children aged 6 to 12 years who referred to the emergency room; Type of blinding: Single-sided blinding; Method of blinding: The research assistant completes the questionnaires after the child leaves the venipuncture room. The research assistant is unaware of the intervention performed in the venipuncture room.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Need for intravenous line placement; willingness of parents and child to participate in the study. Exclusion criteria: Diagnosed cognitive, mental disorders, hearing and vision impairments; The child's condition is urgent.

Intervention groups
Intervention group 1: Virtual reality group: Before the child enters the venipuncture room, virtual reality glasses are placed on the child's face, and the child enters the venipuncture room while watching their favorite animation, and the glasses will remain on the child's face until the end of the procedure. Intervention group 2: Local cold with vibration group: 30 to 60 seconds before the start of venipuncture, a vibrating doll's tourniquet with an ice pack at the bottom is placed 3-5 cm above the venipuncture site and remains in place until the end of venipuncture. Control group: No intervention is performed other than routine care.

Main outcome variables
Pain, fear, anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181214041960N3**
Registration date: **2025-12-12, 1404/09/21**
Registration timing: **prospective**

Last update: **2025-12-12, 1404/09/21**
Update count: **0**

Registration date
2025-12-12, 1404/09/21

Registrant information

Name
Fateme Avizhgan

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-22, 1404/10/01

Expected recruitment end date
2026-02-19, 1404/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effect of virtual reality with a vibrator combined with cold on pain, anxiety, and fear caused by venipuncture children

Public title

Comparing the effects of virtual reality with a vibrator combined with cold on pain, anxiety, and fear caused by venipuncture

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Need for intravenous line Willingness of parents and child to participate in the study

Exclusion criteria:

Diagnosed cognitive and mental disorders, hearing and vision The child's condition is urgent.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **177**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, non-probability and convenience sampling will be used in such a way that samples that meet the inclusion criteria will be included in the study. To randomly assign the sample to three groups (Group A, Group B, Group C), the permutation block allocation method will be used. In this study, blocks will be created in 3 pieces. First, all the states are determined. 1.ABC 2. ACB 3.BAC 4.BCA 5.CAB 6.CBA Then, using the software to determine the permutation blocks, the desired blocks are created from the above 6 blocks using permutation sampling. Finally, 59 blocks of 3 were created, which are presented in a separate file attached to the proposal. In this process, 177 children are examined. In each block, there are three groups A, B, and C.

Blinding (investigator's opinion)

Single blinded

Blinding description

When the child leaves the venipuncture room, the questionnaires are completed by a research associate who is unaware of the type of intervention performed on the child during venipuncture.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Neyshabur University of Medical Sciences

Street address

Neyshabur University of Medical Sciences, End of Eslami Moqavemat Boulevard, Andisheh Town, Neyshabur

City

Neyshabur

Province

Razavi Khorasan

Postal code

9657876543

Approval date

2025-07-20, 1404/04/29

Ethics committee reference number

IR.NUMS.REC.1404.023

Health conditions studied

1

Description of health condition studied

Intravenous line placement

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Before entering the venipuncture room, immediately after leaving the venipuncture room, and 5 minutes after completion of venipuncture.

Method of measurement

Usher Standard Pain Assessment Tool

2

Description

Anxiety

Timepoint

Before entering the venipuncture room, immediately after leaving the venipuncture room, and 5 minutes after completion of venipuncture.

Method of measurement

Observational Scale of Behavioral Distress- Revised

3

Description

Fear

Timepoint

Before entering the venipuncture room, immediately

after leaving the venipuncture room, and 5 minutes after completion of venipuncture.

Method of measurement
Children's Fear Scale (CFS)

Secondary outcomes

1

Description
Pulse

Timepoint
Immediately after completion of venipuncture

Method of measurement
Counting pulse

2

Description
Breathing

Timepoint
Immediately after completion of venipuncture

Method of measurement
Breath counting

Intervention groups

1

Description
Intervention group 1: In the virtual reality group, before the child enters the venipuncture room, headphones and virtual reality glasses are placed on the child's face. The child enters the venipuncture room while watching their favorite animation, and the glasses will remain on the child's face until the end of the procedure.

Category
Behavior

2

Description
Intervention group 2: In the local cold with vibration group, the venipuncture procedure is performed by the responsible nurse 30 to 60 seconds before the start of the venipuncture, 3-5 cm above the venipuncture site, a doll garrote that produces vibration (vibration is performed by a vibration motor placed inside the doll's body). An ice bag is attached to the bottom of it and remains in place until the end of the venipuncture. At the end of each venipuncture, the device is disinfected with a 70% alcohol solution and stored in the ward refrigerator (the ice storage part is separated from the vibrator motor).

Category
Behavior

3

Description
Control group: In the control group, no intervention other than routine care is provided.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Hakim hospital

Full name of responsible person
Fatemeh Avijgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Neyshabour University of Medical Sciences

Full name of responsible person
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golami.123@GMAIL.COM

Grant name

Grant code / Reference number

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

Title of funding source
Neyshabour 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
Neyshabour University of Medical Sciences
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Fatemeh Avijgan
Position
Mentor
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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