

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the Effect of Two Methods of Distraction and Acupressure on Pain and Anxiety of Peripheral Intravenous Cannulation in School-age Pediatric Cancer

Protocol summary

Study aim

Comparison of the effect of two methods of distraction and acupressure on pain and anxiety due to intravenous line insertion in school-age children with cancer.

Design

Cross-over clinical trial with control group, Randomized with Randlist software, single blind , With 30 samples

Settings and conduct

Oncology ward of Tabriz and Urmia Children Hospitals
Entry of samples according to the inclusion criteria
Obtaining written consent Intravenous surgery will be performed by a nurse according to the place of intervention in a fixed room. The grade of pain and anxiety of the child before and after each child will be determined by the child and will be recorded by the researcher . One-sided blind: The statistician will not know the study groups and what the patient has done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Children 6 to 12 years old admitted to oncology ward 2) Full vigilance to place, time and person 3) Ability to communicate verbally 4) Having previous experience of venipuncture 5) Obtain informed consent from the child and parents 6) Health of sight and hearing .Exclusion criteria: 1) Use pain-relieving medication within 8 hours before venereal 2) Enter the catheter more than once into the skin 3) The location of Hugo's point has previous injury and scarring and pain.

Intervention groups

Group A (cartoon): Cartoon playback with VR camera
Group B (Acupuncture): Hugo massage (five minutes before the start of the vein until the end of the intravenous massage line insertion for 1 minute massage and 10 seconds rest). In group C (control), children are routinely given venipuncture.

Main outcome variables

Pain and anxiety score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100823004617N14**

Registration date: **2019-10-18, 1398/07/26**

Registration timing: **retrospective**

Last update: **2019-10-18, 1398/07/26**

Update count: **0**

Registration date

2019-10-18, 1398/07/26

Registrant information

Name

Mahnaz Jabraeili

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-30, 1398/02/10

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effect of Two Methods of Distraction and Acupressure on Pain and Anxiety of Peripheral Intravenous Cannulation in School-age Pediatric Cancer

Public title
"The Effect of Two Methods of Distraction and Acupressure on Pain and Anxiety"

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 12-6 admitted in the oncology department
Full conscious to place, time and person
The ability to communicate verbally
Having a previous experience of peripheral intravenous cannulation
Acquiring informed consent of the child and parents
The health of the eyes and the hearing
Exclusion criteria:
Use of pain relief medications 8 hours prior to peripheral intravenous cannulation
More than one catheter entry into the skin
The location of the Hugo Point has a previous injury and pain. Perform a painful procedure on the baby within 8 hours of the baby's stroke

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: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
This is an experimental study that is a cross-over clinical trial, in which all the specimens are randomly assigned three times under the intravenous insertion procedure with randomized, routine, deviation, and acupressure. Among these three methods, the washout period is considered to be 24 to 72 hours. To conceal allocation, the child is asked to choose one of the opaque envelopes. Each envelope contains a triple block (watch a cartoon movie = A and a Hugo point massage = B) and a control (C) that shows the order of the intervention on the child. These envelopes are already being prepared by a research collaborator using the Randlist software.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyzer does not know how to assign the samples to the study groups.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics committee

Street address

Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947979

Approval date

2019-05-06, 1398/02/16

Ethics committee reference number

IR.TBZMED.REC.1398.115

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain caused by peripheral intravenous cannulation

Timepoint

Before the intervention and after the intervention

Method of measurement

VAS tool

2

Description

Anxiety caused by peripheral intravenous cannulation

Timepoint

Before the intervention and after the intervention

Method of measurement

FAS tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in the intervention method a minute before the onset of intravenous line insertion , the child pain score was determined using the vas scale and the child anxiety score using the fas scale . the child will then be directed to an intravenous line . the sponge bob sponge is placed on the throne of the patient from the time the child is placed on the couch through the virtual space cameras that is placed on the retina of the patient and has the ability to transmit sound and the image . one minute after finishing the insertion , the child 's pain score and anxiety score will be recorded .

Category

Other

2

Description

Intervention group: in method of B , acupressure was determined before informing the child , child pain score using vas scale and child anxiety score using the fas scale . then the child is directed to the insertion of the intravenous line and the child is placed on the vein and then hugo 's point is determined . to determine the point of hugo in the intervention group , the finger of the child 's thumb is referred to the finger and in this case the peak muscle is produced . about five minutes before the procedure and by placing the child on the bed , the point will be massage in a rotating and relaxed position while the child is placed on the sofa by the researcher , so that the maximum pressure time per time is 1 minute and then the massage is discontinued for one minute . the procedure will continue until the procedure is completed . it should be noted that the insertion of the intravenous line in the hands of hugo is performed . one minute after finishing the insertion , the child 's pain score and anxiety score will be recorded .

Category

Other

3

Description

Control group: In the routine procedure, intravenous infusion will be performed as per routine procedure and the child will receive no additional intervention before or during intravenous infusion. Before announcing the baby's intravenous replacement, the child's pain and anxiety score will be determined using one of two scales. The child will then be directed to the IV line room and placed on the IV line bed. Then the child's vein embedding is performed by the researcher. The child's pain and anxiety scores will be recorded again one minute after the intravenous embolization is completed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

children 's hospital in Tabriz University of Medical Sciences

Full name of responsible person

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Web page address

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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

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

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Position

Nursing Master of Science student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

What processes are involved for a request to access data/document

Comments