# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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**
mohammed saeidi

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Sheshgelan Ave

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**2**

**Recruitment center**

**Name of recruitment center**
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mohammed saeidi

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## Sponsors / Funding sources

**1**

**Sponsor**

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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

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**Position**

Nursing Master of Science student

**Latest degree**

Bachelor

**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)**

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**

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**When the data will become available and for how long**

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**To whom data/document is available**

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**Under which criteria data/document could be used**

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**From where data/document is obtainable**

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

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**Comments**