

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the effect of two methods of using toys with medical materials and visual distraction on pain and anxiety during intravenous cannulation in children admitted

Protocol summary

Study aim

Determining and comparing the effect of two methods of toys with medical devices and visual distraction on the intensity of pain and anxiety during venous catheter insertion in children admitted to Ba'ath Medical Education Center in Hamadan

Design

Clinical trial with control group, with parallel groups, single-blinded, randomized, in 150 patients. Allocation was randomized using a block table.

Settings and conduct

Pain during insertion of intravenous catheter in children aged 3-6 years old in Hamadan Besat Medical Center is noted by researcher based on Vang-Baker scale and anxiety based on facial instrument for assessing children's anxiety at the time of insertion of intravenous catheter for each patient. 5 minutes before inserting the venous catheter, in the groups of visual distraction and toys with medical devices, cartoons and games with medical devices, respectively, start and continue until the vein is fixed. There is no intervention in the control group. In this study, the statistical consultant will be blinded by numbering the groups 1 to 3.

Participants/Inclusion and exclusion criteria

An intravenous catheter must be placed in all children admitted to the emergency department or internal paediatric units. In critical cases, such as cardiopulmonary resuscitation or seizures, there is no need to place a venous catheter and...

Intervention groups

Intervention group 1: Visual distraction by playing cartoons during insertion of a venous catheter
Intervention group 2: Playing with medical devices during the insertion of an intravenous catheter
Control group: Non intervention

Main outcome variables

Pain; anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170117032025N10**

Registration date: **2023-08-26, 1402/06/04**

Registration timing: **prospective**

Last update: **2023-08-26, 1402/06/04**

Update count: **0**

Registration date

2023-08-26, 1402/06/04

Registrant information

Name

Arash Khalili

Name of organization / entity

Hamadan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0320

Email address

a.khalili@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparison of the effect of two methods of using toys with medical materials and visual distraction on pain and anxiety during intravenous cannulation in children admitted
Public title	Comparison of the effect of two methods of using toys with medical materials and visual distraction on pain and anxiety during intravenous cannulation in children admitted
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	An intravenous catheter must be placed in all children admitted to the emergency department or internal paediatric units In critical cases, such as cardiopulmonary resuscitation or seizures, there is no need to place a venous catheter and...
Exclusion criteria:	Lack of adequate cooperation (interruption of distraction for more than 2 minutes, agitation of the mother, etc.) on the part of the child and the child's parents
Age	From 3 years old to 6 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Data analyser
Sample size	Target sample size: 150
Randomization (investigator's opinion)	Randomized
Randomization description	Patients are selected by convenience sampling method from patients' records. Then the Balanced Block randomization method will be divided into 3 groups of control (50 children), toys with medical devices (50 children) and visual distraction (50 children).
Blinding (investigator's opinion)	Single blinded
Blinding description	After entering the data, the study groups are numbered 1 to 3 by the researcher, and only numbers 1 to 3 are mentioned in spss, and the data are submitted to the reputable statistical consultant for analysis.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Hamadan University of Medical Sciences
Street address	Shahid Fahmideh Street
City	Hamadan
Province	Hamadan
Postal code	6561058582
Approval date	2023-08-12, 1402/05/21
Ethics committee reference number	IR.UMSHA.REC.1402.388

Health conditions studied	
<u>1</u>	
Description of health condition studied	Pain during intravenous catheter insertion
ICD-10 code	G89.18
ICD-10 code description	Other acute postprocedural pain
<u>2</u>	
Description of health condition studied	Anxiety during intravenous catheter insertion
ICD-10 code	F06.4
ICD-10 code description	Anxiety disorder due to known physiological condition
Primary outcomes	
<u>1</u>	
Description	Pain
Timepoint	During intravenous catheter insertion
Method of measurement	Using the Wang Baker scale
<u>2</u>	
Description	Anxiety
Timepoint	During intravenous catheter insertion
Method of measurement	State Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Visual distraction by playing cartoons during insertion of a venous catheter
Intervention group

Category

Prevention

2

Description

Intervention group 2: Playing with toys with medical devices during the insertion of an intravenous catheter

Category

Prevention

3

Description

Control group: Non intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital, pediatric Wards

Full name of responsible person

Zohreh Fateh

Street address

Besat Hospital, Besat Blvd., Hamedan

City

Hamadan

Province

Hamadan

Postal code

6561058582

Phone

+98 937 753 1808

Email

zohrehfateh75@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Hamedan

City

Hamadan

Province

Hamadan

Postal code

6561065810

Phone

+98 81 3252 0683

Email

MR.shokohi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Arash Khalili

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Pediatrics

Street address

Hamedan University of Medical Sciences, Shahid Fahmideh Blvd., Hamedan

City

Hamadan

Province

Hamadan

Postal code

6517625432

Phone

+98 81 3838 0535

Email

arash5920@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Arash Khalili

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Pediatrics

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Blvd., Hamedan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517625432

Phone

+98 81 3838 0320

Fax

+98 81 3838 0320

Email

arash5920@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Arash Khalili

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Pediatrics

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Blvd., Hamedan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517625432

Phone

+98 81 3838 0320

Fax

+98 81 3838 0320

Email

a.khalili@umsha.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available