Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Effect of watching cartoon on venipuncture induced pain and anxiety in 3-6 year-old children admitted to pediatric ward

Protocol summary

Study aim
Identifying effect of watching cartoon on venipuncture induced pain and anxiety in 3-6 year-old children admitted to pediatric ward

Design
Clinical trial with the intervention and control groups, the samples' number in each group is 70 and totally,140 individuals. Samples will enter the study during the admission days based on inclusion criteria. They will be allocated to one of the groups ,i.e., intervention or control using simple random method with the table of random numbers and based on odd or even number selection .When a group is completed ,the remaining samples are included in another group so that the samples' size gets equal.

Settings and conduct
After sampling, first the children's morbid anxiety is measured. Then the children are led to venipuncture room. The children's pre-and post- venipuncture situational anxiety and pain are immediately measured and finally, the two groups are compared.

Participants/Inclusion and exclusion criteria
Inclusion Criteria :Written prescription for hospitalization ,requiring IV Line ,32-72 months old, Consciousness, creating social communication ,lack of audio-verbal impairments, not mentally retardation , no seizure or any sort of life threatening urgent conditions , the child or parents being willing to participate in the study ,the parents not being a member of health staff , one of the parents accompanying the child Exclusion criteria: The 1st venipuncture attempt in vain, Getting venipuncture in an area other than the back of hand, Using angiocatheter except for No.24, parents or child being reluctant to participate in the study

Intervention groups
For the control group, the routine procedures such as speaking and distracting and etc. are employed. For the intervention group, besides the routines, a cartoon will be displayed for the child throughout the venipuncture.

Main outcome variables
anxiety, pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171203037723N5**
Registration date: **2020-12-16, 1399/09/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-16, 1399/09/26**
Update count: **0**

Registration date
2020-12-16, 1399/09/26

Registrant information

Name
Hamideh Azimi Lolaty

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3336 7343

Email address
azimihamideh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-19, 1399/08/29

Expected recruitment end date
2021-02-17, 1399/11/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of watching cartoon on venipuncture induced pain and anxiety in 3-6 year-old children admitted to pediatric ward

Public title
Effect of watching cartoon on venipuncture induced pain and anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Physician’s written prescription for hospitalizing a child in the pediatric ward Requirment for IV Line for the hospitalized child as prescribed by the physician through written prescription A child throughout 37 -72 months old in both genders Consciousness Capability of creating social communication Lack of audio-verbal impairments Not mentally retardation Lack of seizure or any sort of life threatening urgent conditions Oral and written consent presented by child’s guardian for participating in the study Child’s oral consent for participating in the study Child’s parents not being a member of health staff One of the parents accompanying the child

Exclusion criteria:
The 1st venipuncture attempt in vain Getting venipuncture in an area other than the back of hand Using angiocatheter except for No.24 Parent or child being reluctant to keep participating in the study

Age
From **37 months** old to **72 months** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**
More than 1 sample in each individual
Number of samples in each individual: **2**
A child with a parent

Randomization (investigator's opinion)
Randomized

Randomization description
In case of having the inclusion criteria, the samples will enter the study during admission days and will be allocated to one of the groups ,i.e., intervention and control using Rand Between Excel and will be placed in the groups until sampling gets completed .

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
Ethics Committee of Mazandaran University of Medical Sciences

Street address
Student Research Department, Moallem St., Sari

City
Sari

Province
Mazandaran

Postal code
4815733971

Approval date
2020-10-11, 1399/07/20

Ethics committee reference number
IR.MAZUMS.REC.1399.735

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Pediatric Anxiety Disorders

Timepoint
At the beginning of the study

Method of measurement
Spence Children's Anxiety Scale (SCAS) Parent Version

2

Description
Child’s situational anxiety score

Timepoint
Pre-and post-intervention

Method of measurement
Facial Image Scale (FIS)

3

Description
Child’s pain score

Timepoint
Pre-and post-intervention

Method of measurement
Faces, Legs, Activity, Cry, Consolability (FLACC) Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group:Each child will enter venipuncture room along with a parent. For this group, watching cartoon will be applied besides the routines. Throughout the venipuncture, a tablet is put on the wall displaying the cartoon “The pooches” across from the child.
Category
Other

2

Description
Control Group: Each child enters venipuncture room accompanied with a parent. For control group, the routine procedures such as speaking and distracting and etc. are employed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu Ali Sina Hospital
Full name of responsible person
Hamideh Azimi Lolaty
Street address
Bu Ali Sina Hospital, Imam Sq., Sari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Hamideh Azimi Lolaty
Street address
Nasibeh School of Nursing and Midwifery,Vesal-e-Shirazi Ave.,Amir Mazandarani Blvd.
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Hamideh Azimi Lolaty
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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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
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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