

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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 Requirement 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

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Bu Ali Sina Hospital, Imam Sq., Sari

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+98 11 3334 3010

**Email**

azimihamideh@gmail.com

**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

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

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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