

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The Effect of Distraction Technique on Pain of Venipuncture in 3-6 Year-old Children

#### Protocol summary

##### Summary

Abstract: The present study will be designed and conducted to determine the effect of video game play on pain of venipuncture in 3-6 year-old children. This randomized controlled trial study will be conducted on 80 hospitalized children with pain of venipuncture procedures. Playing a video computer game for children during the venipuncture procedures was the intervention for the interventional group. Also the intensity of pain was measured by behavioral pain scale for children (FLCC scale) during the procedure. This scale will be completed for patients without any intervention in the control group during venipuncture procedures. It seems that video game play intervention has a significant positive effect on the pain of venipuncture procedures in children. Further studies are recommended for the development of this technique in health care centers. Key Words: Distraction, Pain, venipuncture procedure, Children.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016032625029N3**

Registration date: **2016-05-05, 1395/02/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-05, 1395/02/16

##### Registrant information

##### Name

Sima Kaheni

##### Name of organization / entity

Faculty of nursing and medvifry, Mazandaran

University of Medical Sciences, Sari, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3336 7342

##### Email address

s.kaheni@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Deputy of Mazandaran University of Medical Sciences

##### Expected recruitment start date

2016-03-29, 1395/01/10

##### Expected recruitment end date

2016-04-29, 1395/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Distraction Technique on Pain of Venipuncture in 3-6 Year-old Children

##### Public title

The Effect of Distraction Technique on Pain

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: were the age of child 3-6; alertness to place; time and person; having the ability to communicate; not having verbal and auditory disorders; the presence of a parent with the child. Excluded criteria: event of a life-threatening emergency

##### Age

From **2 years** old to **5 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 80

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mazandaran University of Medical Sciences

##### Street address

Moalem Square

##### City

Sari

##### Postal code

4816715793

#### Approval date

2016-02-21, 1394/12/02

#### Ethics committee reference number

IR.MAZUMS.REC.94-1806

## Health conditions studied

### 1

#### Description of health condition studied

Pain of Venipuncture

#### ICD-10 code

Z40,Z41,Z4

#### ICD-10 code description

Persons encountering health services for specific procedures and health care

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before and during the intervention

## Method of measurement

Flacc Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

For the interventional group, 3 minutes before the venipuncture procedures, distraction started by displaying a game on a portable monitor and continued until the end of venipuncture procedures

#### Category

Other

### 2

#### Description

in the control group, venipuncture procedures was done without any intervention.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Bu-Ali Hospital

##### Full name of responsible person

Şima Kaheni

##### Street address

Imam square

##### City

Şari

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Ahmad Ali Enayati

##### Street address

Moalem square

##### City

Sari

#### 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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Sima Kaheni

**Position**

Master degree/Facultymember

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**Web page address**

**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Masou Bagheri nesami

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**City**