

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of cartoon distraction technique on pediatrics preparation pain before suturing in emergency department

Protocol summary

Study aim

Determining the effect of distraction by watching cartoons on the pain of preparation before suturing children in the emergency department

Design

Randomized controlled clinical trial with stratification solution and 86 patients in two groups of intervention and control and randomization with sealed envelopes

Settings and conduct

In the present study, there are two types of cartoons according to the age of children in the age groups of 3 to 6 years and 6 to 12 years. In the intervention group, from the time the child is placed on the bed until the end of the anesthetic injection, the cartoon will be broadcast and in the control group, the cartoon will not be broadcast. The study place is the emergency department of Bu Ali Sina Hospital in Sari

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1 - Rupture in the face less than 3 cm that requires sutures 2- Having a child age of 3-12 years 3 - The presence of the mother next to the child Inclusion criteria: 1- Mental disability 2- Hearing impairment 3- Visual impairment 4- Physical disability 5-Speech Disability 6- Treated mental illness 7- Childhood diabetes 8-Need sedation during suturing 9-Need analgesia during suturing 10- Ruptures sutured by students 11- Child neuromuscular diseases 12- Existence of sensory disorders in the child 13-Need sutures around the eyes

Intervention groups

Intervention group: Playing a cartoon with a tablet by the researcher starts from the time the child is placed on the bed for stitches and continues until the end of the anesthesia injection. Control group: In this group, children are stitched according to the normal routine and cartoons are not broadcast for them.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110906007494N34**

Registration date: **2020-12-07, 1399/09/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-07, 1399/09/17**

Update count: **0**

Registration date

2020-12-07, 1399/09/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cartoon distraction technique on pediatrics preparation pain before suturing in emergency department

Public title

The effect of cartoon distraction technique on pediatrics preparation pain before suture

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Facial laceration less than 3 cm Age of 3-12 years The presence of the mother next to the child

Exclusion criteria:

Mental disability Hearing impairment Visual impairment Physical disability Speech disability Treated mental illness Childhood diabetes A tear that needs sedation during suturing A tear that needs analgesia during suturing Ruptures sutured by students Child neuromuscular diseases Existence of sensory disorders in the child Need sutures around the eyes

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Considering that in this study, two groups A (intervention group) and group B (control group) have been designed, and since sampling should be done based on age and sex, so random sequence based on software by Stratified Block Randomization will be done so that 4 blocks, in the form of blocks 3 to 6 years old girl (11 people in group A and 11 people in group B), blocks 3 to 6 years old boy (11 people in group A and 11 people in group B), blocks 6 to 12 years old girl (11 people in group A and 11 people in group B) and 6 to 12 year old boys (10 people in group A and 10 people in group B). For allocation concealment, 86 opaque envelopes are embedded in the total number of samples, and the first 22 envelopes are numbered from 1 to 22, and the 3 to 6 year old girl is written on it, and the second 22 envelopes are numbered from 1 to 22 And on that block 3 to 6 years old boy is written and the next 22 envelopes are numbered from 1 to 22 and on that block 6 to 12 years old girl is written and the last 20 envelopes are numbered from 1 to 20 and on That block is written for 6 to 12 year old boys, in which A and B cards are placed based on the sequence of the data software.

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

Vice chancellor for research, No 2 building, Mazandran University of Medical Sciences, Moalem street, Moalem square

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2020-08-05, 1399/05/15

Ethics committee reference number

IR.MAZUMS.REC.1399.698

Health conditions studied**1****Description of health condition studied**

Pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

For the intervention and control groups, once after bed rest and the second time during anesthesia injection

Method of measurement

Face Legs Activity Cry Consolability Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: According to the age of the child, the

cartoon is played with the tablet, starting from the time the child is on the bed for suturing and washing the wound, and continues until the end of the anesthesia injection, and the pain is measured with an observational scale of pain behavior in these two stages. Injection of 2% lidocaine in both groups will be injected with a 2 cc syringe and a 23-gauge needle, depending on the child's weight, up to a maximum dose of 5 mg / kg. Two types of cartoons according to the age of children, and considering the Iranian Radio and Television poll among the most watched cartoons and short duration in two age groups of 3 to 6 years (some) with a duration of 8 minutes and in the age group 6 to 12 Year (Grape Gorilla), which lasts 10 minutes, will be broadcast. According to the available statistics, the cartoon of the 3 to 6 year old group was selected from among the most watched polls according to the poll, and the 6 to 12 year old cartoon because the most watched cartoons all had a long duration (about 20 minutes). A 10-minute cartoon was selected by the researcher.

Category
Behavior

2

Description

Control group: In the control group, children will be sutured according to the usual routine and no cartoons will be broadcast to them, and the pain will be measured in the same two stages, ie when the child is lying on the bed for suturing and washing the wound will be.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Bu Ali Sina Hospital, Sari
Full name of responsible person
Mohanna Arablarimi
Street address
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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source

Mazandaran University of Medical Science

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
Dr.Masoumeh Bagheri Nesami
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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

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