

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Investigating the effect of using virtual reality glasses on children's pain intensity and parents' satisfaction of pain management during suturing

Protocol summary

Study aim

Determining the effect of using virtual reality on children's pain intensity and parents' satisfaction with pain management when suturing

Design

A clinical trial with with parallel control group, double-blind, randomize on 60 patients; Excel software was used for randomization.

Settings and conduct

This study is performed in Qazvin Trauma Center Hospital on children with trauma, the method of which was described above.

Participants/Inclusion and exclusion criteria

Study inclusion criteria: the child should be sutured to the limbs and body and referred to Rajai Hospital; age : 5 to 7 years old; no pain or other problem other than the pain of amputation; ability to communicate. Exclusion criteria: any child who did not cooperate during the study (for example, refused to wear glasses or repeatedly removed the glasses from his eyes while stitching); parents who do not answer the research questions correctly. The need to use oral analgesics between suturing procedures.

Intervention groups

Initially, pain intensity in both intervention and control groups will be measured and compared using the instrument (VAS) before the intervention. In the control group, no intervention will be performed and routine affairs will be performed. In the intervention group, virtual glasses will be used 1 to 3 minutes before the start of the suturing procedure, so that a 5-minute animation in which the suturing method is performed. The treatment staff, which also has an educational aspect and is made by a researcher, will be broadcast to the child in 5 minutes in the form of games and animations, and then the intensity of pain will be measured in both groups.

Main outcome variables

Children's pain; cooperation with treatment staff;

parental satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210613051567N1**

Registration date: **2021-08-19, 1400/05/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-19, 1400/05/28**

Update count: **0**

Registration date

2021-08-19, 1400/05/28

Registrant information

Name

Mahya Farmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using virtual reality glasses on children's pain intensity and parents' satisfaction of pain management during suturing

Public title

Evaluation of the effect of virtual glasses on children's pain intensity and parental satisfaction

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The child should be sutured to the limbs and body and referred to Rajai Hospital Age: 5 to 7 years old No pain or other problem other than the pain of amputation Ability to communicate No vision or hearing problems (based on initial history) No psychological problems or mental retardation (based on initial history) Do not use oral or injectable analgesics before entering the hospital

Exclusion criteria:

Any child who did not cooperate in the study (for example, refrained from wearing glasses or repeatedly removed glasses from their eyes while suturing) Parents who do not answer the research questions correctly. The need to use oral analgesics between suturing procedures.

Age

From **5 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the samples are divided into simple and individual randomizations and first, on 60 pieces of paper, the number 1 was written as a sign of the intervention group or 2 as a sign of the control group. The papers were packed in small envelopes that looked exactly like each other, placed in a box, and when each child entered the ward, each child randomly selected one of the envelopes in the box and according to selected number 1 or 2 was placed in the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Use virtual glasses to play 3D educational animation

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tehran University of Medical Sciences

Street address

Nursing and Midwifery School of Tehran University of Medical Science; Mirkhani Street; Towhid Square, Tehran Town

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.TUMS.FNM.REC.1400.038

Health conditions studied

1

Description of health condition studied

Severe pain when the limb is sutured

ICD-10 code

G89.21

ICD-10 code description

Chronic pain due to

Primary outcomes

1

Description

Pain intensity during suturing and parental satisfaction with pain management

Timepoint

Pain intensity is measured half an hour before and immediately after suturing

Method of measurement

VAS pain measurement tool VAS and satisfaction is measured by a researcher-made questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: initially, pain intensity in the

intervention group will be measured and compared using the instrument (VAS) before the intervention. In the intervention group, before entering the suture room, the correct use of glasses will be fully explained to children and parents, and then virtual glasses will be used 1 to 3 minutes before the start of the suturing procedure. A 5-minute animation in which the method of suturing by the medical staff, which also has an educational aspect and is made by a researcher, will be broadcast in 5 minutes as a game and animation for the child, and if the animation is completed and the procedure continues (which Usually lasts 5 to 10 minutes), the animation will be repeated and after the stitches are done, the glasses will be removed from the child's eyes and the severity of the child's pain will be measured. After suturing in the intervention group, it will be measured using a pain intensity test (Visual Analogue Scale). During the whole suturing work, one of the parents will be present with the child in the intervention group. All parents 'satisfaction will be measured using the Parents' Satisfaction Questionnaire for pain management half an hour after the intervention and suturing. Demographic information will also be asked of parents at the beginning of the sampling.

Category

Treatment - Devices

2

Description

Control group: 30 children will be randomly selected in the control group and the routine of the hospital will be performed for them and lidocaine will be used for anesthesia, but virtual glasses will not be used. After suturing the pain questionnaires (VAS) and parents' satisfaction with pain management, the child and parents will be given to collect data.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin Truma Rajai Hospital

Full name of responsible person

Mahya Farmani

Street address

Shahid Rajaei Hospital, Safdari Alley, Padgan St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akram Sadat Hosseini

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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

Tehran University of Medical Sciences

Proportion provided by this source

50

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

Tehran University of Medical Sciences

Full name of responsible person

Mahya Farmani

Position

master student of pediatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Position

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Latest degree

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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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data are collected through two questionnaires of VAS and parental satisfaction with pain management and the results of the data are analyzed by skilled people and the pain is at the discretion of professors and treatment staff to use its beneficial results.

When the data will become available and for how long

After collecting the samples and analyzing them by statistical software, it will be possible to access the data results. The obtained data is also available during sampling

To whom data/document is available

Researchers, professors, consultants, supervisors, and treatment staff at the sampling site are allowed to access the data

Under which criteria data/document could be used

In order to improve the performance of the treatment staff and reduce stress and stress and pain of children and their families and in the conditions of achieving the expected results, the data can be used.

From where data/document is obtainable

To receive the documents and data after analyzing them, refer to the researcher or Tehran University of Medical Sciences

What processes are involved for a request to access data/document

To receive documents and data, the applicant can access the data by email to the researcher or by referring to Tehran University of Medical Sciences and learning the researcher's dissertation.

Comments