

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effect of Watching Dental and Non-Dental-Related Animations on Pain and Anxiety in 6-8 Year Old Children During Mandibular Nerve Block Injection

Protocol summary

Study aim

Comparing the effect of animations related and not related to dentistry on the amount of pain and anxiety of 6-8 year old children during mandibular nerve block injection.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, on 48 patients. A simple individual method was used for randomization.

Settings and conduct

For patients referring to the pediatric department of Zahedan Dental School, a profile form will be filled. In the first group, from 15 minutes before the start of the treatment, the related animation will be played, in the second group, from 15 minutes before the start of the treatment, an unrelated animation will be played (in a quiet environment) and in the third group, no animation will be played for the child (control group).). For the purpose of blinding in this research, the operator, evaluator, and patient will be unaware of the type of intervention. Children will be included in the intervention group by a dental student and will be monitored during the research process.

Participants/Inclusion and exclusion criteria

Children referred to Zahedan pediatric department who are 6 to 8 years old, the patient is not sensitive to anesthetics, the presence of at least one molar requires non-emergency treatment and mandibular occupational therapy, the absence of a history of special diseases and being healthy, having normal intelligence. , Frankel grade 3 and 4, the patient has no history of dental treatment and no previous observation of any of the two animations used in this study will be included in the study, and the non-entry is Frankel grade 1 and 2 and the use of any pain reliever and have sedation 48 hours before injection

Intervention groups

First intervention group: related animation The second intervention group: irrelevant animation Control group: no animation

Main outcome variables

Level of anxiety; intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220726055560N1**

Registration date: **2022-11-11, 1401/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-11, 1401/08/20**

Update count: **0**

Registration date

2022-11-11, 1401/08/20

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Watching Dental and Non-Dental-Related Animations on Pain and Anxiety in 6-8 Year Old Children During Mandibular Nerve Block Injection

Public title

Effect of watching animation in children's dentistry

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 6 to 8 years The presence of at least one asymptomatic molar requires non-emergency treatment and occupational therapy under mandibular nerve block anesthesia. Absence of history of specific diseases and being healthy at the time of entering the study Having natural intelligence (based on the child's behavior and speech) The patient should be Frankel grade 3 or 4 in terms of cooperation The patient does not have a history of dental treatment No previous viewing of any of the two animations used in this study

Exclusion criteria:

The patient should be Frankel grade 1 and 2 in terms of cooperation During the study, the presence of a medical problem or the occurrence of certain diseases is diagnosed Taking any pain reliever and sedative 48 hours before the injection Dissatisfaction of parents to participate in this study Allergy to anesthesia

Age

From **6 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

People were divided into three blocks of 8. Each block corresponded to one of three groups of related animation, unrelated animation, and control, into which subjects were assigned by selecting sealed envelopes. Randomization method: limited (block). This method is used to create groups with equal numbers Randomization Unit: Individual Layers of randomization in case of using layered randomization: none Randomization tool: sealed envelope Creating a random sequence using Random allocation software Opaque sealed envelopes with random sequence are used for

concealment. In this method, a number of letter envelopes are prepared with aluminum foil (for the lack of clarity of the contents of the envelopes), and each of the random sequences created is recorded on a card and the cards are placed inside the letter envelopes in order. In order to preserve the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box in order. Then the participants take one of the letter envelopes and open them, and the assigned group of that participant is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Before entering the therapy department, children enter the room to watch the animation and then enter the therapy department with or without watching the animation. Therefore, the outcome assessor and the therapist are not aware of the conditions and do not have the right to question the child in this regard. Also, due to the coding of questionnaires and not determining the type of intervention, the analyst does not know the ratio of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zahedan University of Medical Sciences

Street address

Dr. Hasabi Square - Medical Sciences Pardis

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Zahedan

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Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2022-09-04, 1401/06/13

Ethics committee reference number

IR.ZAUMS.REC.1401.200

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

Pulp disease

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes**1****Description**

Anxiety severity based on Venham test

Timepoint

Only when injecting local anesthesia

Method of measurement

Using Venham's visual test

2**Description**

Pain intensity based on Sound-Eye-Motor Scale (SEM)

Timepoint

Only when injecting local anesthesia

Method of measurement

Using the SEM scale

Secondary outcomes

empty

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

The first intervention group: once broadcast animation related to dentistry (practice in dentistry) for 15 minutes before starting the treatment in a quiet environment.

Category

Behavior

2**Description**

The second intervention group: once broadcast an animation not related to dentistry (mustrabin-hot sauce challenge) for 15 minutes before starting the treatment in a quiet environment.

Category

Behavior

3**Description**

Control group: patient entering the treatment room without playing the animation

Category

Behavior

Recruitment centers**1****Recruitment center**

Name of recruitment center

Department of Pediatrics, Zahedan Faculty of Dentistry

Full name of responsible person

Masoume Danesh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Nur Mohammad Bakhshani

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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

Vice President of Research, Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Masoume Danesh

Position

Faculty member

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

There is no further 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