

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison effect of virtual reality glasses and audio distraction in reducing anxiety and pain during inferior alveolar nerve block in children aged 7 to 10 years

Protocol summary

Study aim

Comparison effect of virtual reality glasses and audio distraction in anxiety and pain during inferior alveolar nerve block in children aged 7 to 10 years

Design

The randomized clinical trial study will be conducted in the form of three parallel groups (two intervention groups and one control group). Since the nature of the intervention was not able to conceal the samples and researchers, blinding will not be applicable in this study. The random function of Excel software will be used for randomization.

Settings and conduct

A sample of 45 children aged 7-10 years will be selected by available sampling from among the children referred to the Yazd Dental School clinic and need inferior alveolar nerve block. Heart rate and blood pressure will be measured before and after the injection. We measure blood pressure and heart rate before and after injection in all three groups and use three questionnaires to measure pain and anxiety subjectively.

Participants/Inclusion and exclusion criteria

7-10 year old children referred to the pediatric department of Yazd University of Medical Sciences Faculty of Dentistry. The inclusion criteria include the presence of caries in the mandibular deciduous teeth that require lower alveolar block injection, no history of intraoral injection, no allergy to lidocaine, no history of pain due to pulp inflammation, no primary anxiety disorder and no unsuccessful and unfavorable experience in It was subject to medical treatment.

Intervention groups

In the first intervention group, the child uses virtual reality glasses during anesthesia injection. In the second intervention group, the child uses headphones during anesthesia injection. In the control group, injections are performed routinely.

Main outcome variables

FLACC index score; WBFP index score; changes in blood pressure; heart rate changes; FIS index score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230614058486N1**

Registration date: **2023-06-24, 1402/04/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-24, 1402/04/03**

Update count: **0**

Registration date

2023-06-24, 1402/04/03

Registrant information

Name

Kazem Vaez

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 0820 4050

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-18, 1402/03/28

Expected recruitment end date

2023-08-19, 1402/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of virtual reality glasses and audio distraction in reducing anxiety and pain during inferior alveolar nerve block in children aged 7 to 10 years

Public title

Comparison effect of virtual reality glasses and audio distraction in reducing anxiety and pain during inferior alveolar nerve block in children aged 7 to 10 years

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The presence of caries in the mandibular primary teeth that requires inferior alveolar nerve block injection

Exclusion criteria:

history of intraoral injection allergic to Lidocaine History of pain due to pulp inflammation Primary anxiety disorder Unsuccessful and adverse experience with medical treatments History of anesthesia injection

AgeFrom **7 years** old to **10 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **45****Randomization (investigator's opinion)**

Randomized

Randomization description

A statistical consultant, who had no role in patient selection or outcome evaluation, prepared three lists of 15 people. Three lists were generated by simple random sampling using computer randomization methods. This list showed the type of injection in the treatment session. Patients were assigned a number based on the order of referral, and this number was one of the interventions based on which of the three lists it was located in.

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 Yazd University of Medical Sciences

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No. 5, sixth floor, block A, Noor tower , jam e jam Ave., Sameyi Blvd.

City

Yazd

Province

Yazd

Postal code

8949193118

Approval date

2022-12-24, 1401/10/03

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1401.072

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

pain and anxeity

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

Pain and anxiety using: FLACC index score; WBFP index score; changes in blood pressure; heart rate changes; FIS index score

Timepoint

Before and immediately after the intervention

Method of measurement

Pain and stress using: FLACC index score; WBFP index score; changes in blood pressure; Changes in heart rate with wrist sphygmomanometer and FIS index score

Secondary outcomes

empty

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

Intervention group: Intervention group: In the first intervention group, the child uses virtual reality glasses during anesthesia injection. Tools used in virtual reality include audio-visual glasses connected to a mobile phone that will play a similar cartoon during dental treatment.

Category

Treatment - Devices

2

Description

Intervention group: Second intervention group: For children participating in the second intervention group, there is no picture and only the sound of the cartoon will be played (headset).

Category

Treatment - Devices

3

Description

Control group: In the control group, the work is done without any of these devices and with usual and routine distraction methods for the patient.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of pediatric dentistry, Yazd Faculty of Dentistry

Full name of responsible person

Kazem Vaez

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amin Salehi Abarghouei

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Zahra bahrololoomi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available