Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Impact of Virtual Reality Technique on level of Pain and Anxiety during Pulpotomy of Primary molar teeth

Protocol summary

Summary
The present study has evaluated the Behavioral Feedback of 6-10 Years pediatric dental patients by Using Virtual Reality Technique during Pulpotomy of Primary molar teeth.20 children, aged 6–10 years, and attending at have taken part in this study. Participants have been studied in one of the two groups randomly under the similar conditions (time and place). Pulpotomies have been done in a mandible by a dentist resident.In first session, all patients of first group experienced virtual reality of Pulpotomy and in second session's palputomy was without virtual reality technique, but in the second group, treatment sessions have been designed conversely. The amount of pain by Wong-Baker Faces Pain Rating Scale and the child's behavior by Frankle scale has been evaluated by a dentist surveillant of pulpotomy. In addition, blood pressure and Heart rate criteria of patients have been measured before shot and after the procedure.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2014122420413N1**
Registration date: **2015-01-31, 1393/11/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2015-01-31, 1393/11/11

Registrant information
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Negar Mohammadi
Name of organization / entity
Qazvin university of medical sciences
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Recruitment status
Recruitment complete
Funding source
Deputy of Research of Qazvin University of Medical Sciences

Expected recruitment start date
2014-12-22, 1393/10/01
Expected recruitment end date
2015-02-20, 1393/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Impact of Virtual Reality Technique on level of Pain and Anxiety during Pulpotomy of Primary molar teeth

Public title
Evaluation of Behavioral Feedback of 6-10 Years pediatric dental pateints by Using Virtual Reality Technique during Pulpotomy of Primary molar teeth
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: 6-10 years old children;The Existence of two carious primary molars (D or E) in the maxilla or mandible necessitating Pulpotomy;Not to have Unpleasant Not to have experiences in medical settings; Not to have Any experience in dental treatment, audiovisual disorders; Not to have Mental and physical disorders; Not to have Childhood anxiety related

disorders; Not to have Allergies to Lidocain. Exclusion criteria: Toxic children; Treatment time which lasts more than 30 minutes If the patient needs more than one anesthesia; Children who have gag reflex;Children who need pulpectomy during treatment.

Age
From **6 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin University of Medical Sciences

Street address
faculty of dentistry,Qazvin University of Medical Sciences, Bahonar Blv

City
Qazvin

Postal code
3881969183

Approval date
2014-06-11, 1393/03/21

Ethics committee reference number
8839/20/28

Health conditions studied

1

Description of health condition studied
situational anxiety

ICD-10 code
f93.8

ICD-10 code description
Other childhood emotional disorders

2

Description of health condition studied
pain(tooth pain)

ICD-10 code
k08.8

ICD-10 code description
Other specified disorders of teeth and supporting structures

Primary outcomes

1

Description
systolic and diastolic Blood Pressure and Hart Rate

Timepoint
Before and After pulpotomy

Method of measurement
Pediatric Blood Pressure Monitor with Cuff

2

Description
pain

Timepoint
before and after pulpotomy

Method of measurement
Wong-Baker Fasces Pain Rating and frankle scale

3

Description
child’s behavior

Timepoint
before and after pulpotomy

Method of measurement
Frankle scale

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group: during Local Anesthesia injection and Pulpotomy used an audiovisual eye glasses system (Model: 3D X-Mage VG 601) with internal memory and showed TOM & GERRY cartoon that It is very popular among children.

Category
Behavior

2

Description
The control group: underwent injection with no intervention during Pulpotomy

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty od dentistry, Qazvin University of Medical sciences

Full name of responsible person
Negar mohammadi

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faculty of dentistry,Qazvin University of Medical Sciences, Bahonar Blv

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of Research of Qazvin University of Medical Sciences

Full name of responsible person
Dr Asef Zadeh

Street address
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City
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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
Deputy of Research of Qazvin 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
Faculty od dentistry, Qazvin University of Medical sciences

Full name of responsible person
Negar mohammadi

Position
Dentistry Doctor

Other areas of specialty/work

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Bachelor of Science in Nursing

Other areas of specialty/work

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Position
Dentistry Doctor

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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