

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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 pulpotomy 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

Name

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 patients 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 Fases 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 of 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

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

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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 of 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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Dentistry Doctor

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>