

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of the effect of oral sweet taste on pain level of maxillary infiltration anesthesia in children 6-9 years old

Protocol summary

Study aim

Evaluation of the effect of oral sweet taste on the pain level caused by infiltration anesthesia of the first maxillary molar in children 6-9 years old

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized on 32 patients, a simple randomization method with a sealed envelope will be used for randomization.

Settings and conduct

Children aged 6-9 years in the pediatric ward of Qazvin Dental School who need pulp treatment of maxillary primary molar are enrolled according to inclusion & exclusion criteria. The intervention group receives 25% sucrose solution for two minutes & control group receives drinking water before injection. The evaluator encounters the child after preparation (evaluator blinding) and the data is provided to the statistical analyzer in the form of group code (analyzer blindness).

Participants/Inclusion and exclusion criteria

Children aged 6-9 years who need pulp treatment for the first maxillary primary molars, who are healthy and cooperative, are included in the study and are excluded from the study in case of any allergies or problems with sweets or acute dental conditions.

Intervention groups

In the first session, children receive brushing and fluoride therapy to shape their behavior, and in the next session, after using the tell-show-do technique, they undergo infiltration in the area of the first maxillary molars. The intervention group receives 25% sweet solution (25 g of sucrose (Merck, Germany) -75 cc of distilled water) before performing the work. The child is asked to hold the solution in the mouth for two minutes. In the control group, this is done with ordinary drinking water

Main outcome variables

Objective evaluation according to FLACC criteria;
Subjective evaluation according to Wong Baker criteria;
Heart rate; Degree of blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180104038218N2**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Razieh Jabbarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3335 3061

Email address

r.jabbarian@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral sweet taste on pain level of maxillary infiltration anesthesia in children 6-9 years old	
Public title	Evaluation of the effect of oral sweet taste on pain level of upper jaw anesthesia in children 6-9 years old
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Children 6-9 years old requiring pulp treatment of maxillary first molar Physical health in terms of systemic and developmental Positive behavior according to Frankle classification (cooperative and without resistance to treatment) Do not eat or drink anything for at least one hour before the injection Exclusion criteria: Allergies or contraindications to the use of sweets The presence of spontaneous / nocturnal pain or abscess in the desired tooth Pain, inflammation and any other problems in the injection site
Age	From 6 years old to 9 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Outcome assessor • Data analyser
Sample size	Target sample size: 32
Randomization (investigator's opinion)	Randomized
Randomization description	Simple randomization using an sealed envelope with an equal number of intervention (sweet taste) and control (water) samples is placed in a package and provided to the ward nurse, each time the nurse (Who has no role in the continuation of the study) pulls one of the envelopes and it is determined that the patient receives intervention or control.
Blinding (investigator's opinion)	Double blinded
Blinding description	Outcome assessment is performed by a person other than the researcher and clinical caregiver and because he / she is present at the patient's bedside after the intervention, he / she is blind to the received intervention. The grouping results of each sample are delivered to the statistical analyzer in the form of numbers.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Bahonar Boulevard

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2021-08-21, 1400/05/30

Ethics committee reference number

IR.QUMS.REC.1400.231

Health conditions studied

1

Description of health condition studied

Injection in pediatric dentistry

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Objective level of pain

Timepoint

After completion of anesthesia

Method of measurement

Face,leg,activity,crying,consolability (FLACC)

2

Description

Subjective level of pain

Timepoint

After completion of anesthesia

Method of measurement

Wong Baker

3

Description

Heart rate

Timepoint

Before, during and after injection

Method of measurement

Pulse oximeter

4**Description**

Blood level of oxygen saturation

Timepoint

Before, during and after injection

Method of measurement

Pulse oximeter

Secondary outcomes

empty

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

Intervention group: In the first session, children receive brushing and fluoride therapy to shape their behavior, and in the next session, after using the tell-show-do technique, they undergo infiltration in the area of the first maxillary molars. The intervention group receives 25% sweet solution (25 g of sucrose (Merck, Germany) -75 cc of distilled water) before performing the work. The child is asked to hold the solution in the mouth for two minutes. The injection technique in both groups was the same, first by applying a topical benzocaine gel (20%) to the mucosa for one minute and then a cartridge of 1.8 ml of 2% lidocaine + epinephrine 1: 80000 (Daroupakhsh, Iran) and a needle. 25 mm with gauge 27 (Sirio, Italy). After pulling the mucosa, the needle is inserted at a 45 degree angle of 1-2 mm into the mucosa and a few drops are injected. After aspiration, more progress is made and the injection is completed. All injections are given by one person.

Category

Treatment - Other

2**Description**

Control group: In the first session, children receive brushing and fluoride therapy to shape their behavior, and in the next session, after using the tell-show-do technique, they undergo infiltration in the area of the first maxillary molars. The intervention group receives regular drinking water before performing the work. The child is asked to hold water in the mouth for two minutes. The injection technique in both groups was the same, first by applying a topical benzocaine gel (20%) to the mucosa for one minute and then a cartridge of 1.8 ml of 2% lidocaine + epinephrine 1: 80000 (Daroupakhsh, Iran) and a needle. 25 mm with gauge 27 (Sirio, Italy). After pulling the mucosa, the needle is inserted at a 45 degree angle of 1-2 mm into the mucosa and a few drops are injected. After aspiration, more progress is made and the injection is completed. All injections are given by one person.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Qazvin university of medical sciences, Faculty of dentistry

Full name of responsible person

Razieh Jabbarian

Street address

Bahonar Boulevard

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3335 3062

Email

r.jabbarian@qums.ac.ir

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

Qazvin University of Medical Sciences

Full name of responsible person

Dr Mehdi Mirhashemi

Street address

Shahid Beheshti boulevard

City

Qazvin

Province

Qazvin

Postal code

13911/34156

Phone

+98 28 7777 3333

Email

sm.mirhashemi@qums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin 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

+98 28 3335 3062

Email

r.jabbarian@qums.ac.ir

Person responsible for general inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Razieh Jabbarian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Bahonar Boulevard

City

Qazvin

Province

Qazvin

Postal code

3471976160

Phone

+98 28 3335 3062

Email

r.jabbarian@qums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Razieh Jabbarian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Bahonar Boulevard

City

Qazvin

Province

Qazvin

Postal code

3471976160

Phone

+98 28 3335 3062

Email

r.jabbarian@qums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Razieh Jabbarian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Bahonar Boulevard

City

Qazvin

Province

Qazvin

Postal code

3471976160

Phone**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