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 Boulvard

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 Boulvard
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 boulvard
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

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 Boulvard
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 Boulvard
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 Boulvard
City
Qazvin
Province
Qazvin
Postal code
3471976160
Phone
+98 28 3335 3062
Email
r.jabbarian@qums.ac.ir

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