

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluating the efficacy of oral sweet taste in making dental treatment of 4-6 years old children more pleasant

Protocol summary

Study aim

Evaluating the efficacy of oral sweet taste in making dental treatment of 4-6 years old children more pleasant

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized on 40 patients, a simple randomization method with a sealed envelope

Settings and conduct

Patients of pediatric ward of Qazvin Dental School are included in the study according to the inclusion and exclusion criteria. The oral environment of the intervention group is maintained sweet with a solution of 25% sucrose and honey before and during the treatment. Water is used in the control group. After preparing the child, the evaluator meets him (blinding of the evaluator) and the data is provided to the statistical analyst in the form of group code (blinding of the analyst).

Participants/Inclusion and exclusion criteria

4-6 year old children who need pulp treatment of maxillary primary molar who are healthy and cooperative are included in the study. In case of any allergy or problem with sweet substances, the presence of spontaneous/night pain or the presence of inflammation in the target tooth, or the lack of proper anesthesia, the patient will be excluded from the study.

Intervention groups

In the intervention group, after anesthesia injection, the child keeps 25% sweet solution in the mouth for one minute and then, honey is placed in the buccal vestibule of the mandible, in the opposite quadrant, with a swab. This operation is repeated every 2 minutes. In the control group, after anesthesia injection, the child keeps normal water in his mouth for one minute and takes it out. During the treatment, a dry swab is drawn in the buccal vestibule on the opposite side of the treatment and this is repeated every two minutes

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: **IRCT20180104038218N4**

Registration date: **2022-09-18, 1401/06/27**

Registration timing: **prospective**

Last update: **2022-09-18, 1401/06/27**

Update count: **0**

Registration date

2022-09-18, 1401/06/27

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

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Not used
Scientific title	Assignment
Evaluating the efficacy of oral sweet taste in making dental treatment of 4-6 years old children more pleasant	Parallel
	Other design features
Public title	Secondary Ids
Evaluating the efficacy of oral sweet taste in making dental treatment of 4-6 years old children more pleasant	empty
Purpose	Ethics committees
Treatment	
Inclusion/Exclusion criteria	1
Inclusion criteria:	Ethics committee
4-6 year old children in need of maxillary first molar pulp treatment Physical health in terms of systemic and development positive behavior according to Frankel's classification (cooperative and without resistance to treatment) They should not eat or drink anything at least one hour before the treatment Without previous dental experience	Name of ethics committee
Exclusion criteria:	Ethics Committee of Qazvin University of Medical Sciences
Allergy or contraindication regarding consumption of sweet substances Spontaneous/nocturnal pain or abscess in the target tooth Presence of pain, inflammation and any other problem in the treatment area If complete anesthesia was not achieved for the treatment, the patient will be excluded from the study	Street address
	Bahonar Boulevard
	City
	Qazvin
	Province
	Qazvin
	Postal code
	3419759811
Age	Approval date
From 4 years old to 6 years old	2022-08-03, 1401/05/12
Gender	Ethics committee reference number
Both	IR.QUMS.REC.1401.131
Phase	Health conditions studied
N/A	
Groups that have been masked	1
- Outcome assessor - Data analyser	Description of health condition studied
	treatment in pediatric dentistry
Sample size	ICD-10 code
Target sample size: 40	G89.1
Randomization (investigator's opinion)	ICD-10 code description
Randomized	Acute pain, not elsewhere classified
Randomization description	Primary outcomes
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.	1
Blinding (investigator's opinion)	Description
Double blinded	The objective level of pleasant treatment
Blinding description	Timepoint
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, so the analyzer is also blind. According to the sweet taste in the mouth of the intervention group, the participants are not blind.	during treatment
	Method of measurement
Placebo	FLACC(Face,leg,activity,crying,consolability)
	2
	Description
	The objective level of pleasant treatment
	Timepoint
	after treatment
	Method of measurement
	Wong baker

3

Description

heart rate

Timepoint

before, during and after treatment

Method of measurement

pulse oximeter

4

Description

oxygen saturation

Timepoint

before, during and after treatment

Method of measurement

pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In the first session, all children are subjected to brushing treatment and fluoride therapy with the tell show do technique in order to evaluate cooperation and shape their behavior. In the next session, the child is randomly assigned to one of the first and second groups and receives dental treatment. In both groups, 2% lidocaine and 1/100,000 epinephrine were used to anesthetize the region with the supra periosteal technique, and the injection syringe was not placed in the child's viewing angle in both groups. In the intervention group, pulp therapy of the maxillary molar is performed in the condition where sweet taste prevails in the mouth; Therefore, after anesthesia injection, the child kept a 25% sweet solution (25 g of sucrose (Merck, Germany) - 75 cc of distilled water) in the mouth for one minute, and then, honey is applied with a swab in the buccal vestibule of the mandible, in the opposite quadrant. If the honey is washed, this process is repeated every 2 minutes

Category

Treatment - Other

2

Description

Control group: Control group: In the first session, all children are subjected to brushing and fluoride therapy with the tell show do technique in order to evaluate cooperation and shape their behavior. In the next session, the child is randomly assigned to one of the first and second groups and receives dental treatment. In both groups, 2% lidocaine and 1/100,000 epinephrine were used to anesthetize the region with the supra periosteal technique, and the injection syringe was not placed in the child's viewing angle in both groups. In the control group, the maxillary molar receives pulp therapy

under normal conditions. In control group , after the anesthetic injection, the child holds normal water in his mouth for one minute and then spits it out. During the treatment, a dry swab is drawn in the buccal vestibule on the opposite side of the treatment and this is repeated every two minutes.

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

Bahonar 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?**

No

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**

Other

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 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

+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

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