

# 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                                                  |
| <b>Scientific title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Assignment</b>                                         |
| Evaluating the efficacy of oral sweet taste in making dental treatment of 4-6 years old children more pleasant                                                                                                                                                                                                                                                                                                                                                          | Parallel                                                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Other design features</b>                              |
| <b>Public title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Secondary Ids</b>                                      |
| Evaluating the efficacy of oral sweet taste in making dental treatment of 4-6 years old children more pleasant                                                                                                                                                                                                                                                                                                                                                          | empty                                                     |
| <b>Purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Ethics committees</b>                                  |
| Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                           |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>1</b>                                                  |
| <b>Inclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Ethics committee</b>                                   |
| 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                                                                                                                    | <b>Name of ethics committee</b>                           |
| <b>Exclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                              | 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                                                                                                                                                       | <b>Street address</b>                                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Bahonar Boulevard                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>City</b>                                               |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Qazvin                                                    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Province</b>                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Qazvin                                                    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Postal code</b>                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 3419759811                                                |
| <b>Age</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Approval date</b>                                      |
| From <b>4 years</b> old to <b>6 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                           | 2022-08-03, 1401/05/12                                    |
| <b>Gender</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Ethics committee reference number</b>                  |
| Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | IR.QUMS.REC.1401.131                                      |
| <b>Phase</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Health conditions studied</b>                          |
| N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                           |
| <b>Groups that have been masked</b>                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>1</b>                                                  |
| <ul style="list-style-type: none"> <li>Outcome assessor</li> <li>Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                               | <b>Description of health condition studied</b>            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | treatment in pediatric dentistry                          |
| <b>Sample size</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>ICD-10 code</b>                                        |
| Target sample size: <b>40</b>                                                                                                                                                                                                                                                                                                                                                                                                                                           | G89.1                                                     |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>ICD-10 code description</b>                            |
| Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Acute pain, not elsewhere classified                      |
| <b>Randomization description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Primary outcomes</b>                                   |
| 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.                                                                                                           | <b>1</b>                                                  |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Description</b>                                        |
| Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                          | The objective level of pleasant treatment                 |
| <b>Blinding description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Timepoint</b>                                          |
| 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                                          |
| <b>Placebo</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Method of measurement</b>                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | FLACC( Face,leg,activity,crying,consolability)            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>2</b>                                                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Description</b>                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | The objective level of pleasant treatment                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Timepoint</b>                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | after treatment                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Method of measurement</b>                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 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**

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**Province**

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**Postal code**

13911/34156

**Phone**

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**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

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Qazvin

**Province**

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**Postal code**

3471976160

**Phone**

+98 28 3335 3062

**Email**

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**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

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

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**Position**

Assistant Professor

**Latest degree**

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**Province**

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**Postal code**

3471976160

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**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