

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### **Efficacy and acceptance of a new local anesthesia technique (needleless injection) with the conventional technique in the management of maxillary deciduous teeth**

#### **Protocol summary**

##### **Study aim**

Determining Efficacy and acceptance of a new local anesthesia technique (needleless injection) with the conventional technique in the management of maxillary deciduous teeth

##### **Design**

The study is a cross-over clinical trial of 30 children in need of restorative treatments in maxillary primary molars using a standard needle-less injection technique and a randomized, double-blinded study.

##### **Settings and conduct**

This study, which is carried out in the pediatric ward of Campus of Tehran Dental School, in each case, one new molar tooth is anesthetized by the new method and the other one is anesthetized by the conventional method.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria Children aged 6 to 12 years with decayed primary molar on both sides of the maxilla who need anesthesia repair and their parents are satisfied after studying the consent form. The exclusion criteria are children who are so uncooperative that the university refuses to accept them, as well as children who have any systemic, infectious or viral illness.

##### **Intervention groups**

In this study, the efficacy and acceptability of anesthesia was evaluated by a new (needle-free) method. In one primary molars, this method was used for anesthesia and in the other primary molars, the most common anesthesia was used.

##### **Main outcome variables**

Child sympathy / pain / leg movements / facial expressions / child activity / crying

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20191015045116N1**

Registration date: **2020-04-12, 1399/01/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-12, 1399/01/24**

Update count: **0**

##### **Registration date**

2020-04-12, 1399/01/24

##### **Registrant information**

###### **Name**

Maryam alsadat Mousavi bagheri

###### **Name of organization / entity**

###### **Country**

Iran (Islamic Republic of)

###### **Phone**

+98 21 2248 8305

###### **Email address**

hananehgolparvar72@gmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2020-03-15, 1398/12/25

##### **Expected recruitment end date**

2020-04-13, 1399/01/25

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

##### **Scientific title**

Efficacy and acceptance of a new local anesthesia technique (needleless injection) with the conventional

technique in the management of maxillary deciduous teeth

#### Public title

Comparison of the efficacy of non-needle and needle anesthesia (common dental anesthesia)

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Children aged 6 to 12 years. These children have decayed primary molar on both sides of the maxilla. These decayed primary molars require restorative treatment. The repair of these decayed primary molars requires anesthesia.

##### Exclusion criteria:

children who are so uncooperative that the university refuses to accept them. Children who have any systemic or infectious or viral diseases.

#### Age

From **6 years** old to **12 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Care provider
- Investigator

#### Sample size

Target sample size: **25**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two decayed primary molars in the maxilla, each anesthetized with two separate treatment sessions.

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The randomization process in this study is a quadruple block design. In this way, we have four modes for intervention, including the left maxillary anesthesia needle / left maxillary anesthesia needle / right maxilla anesthesia needleless needle / right maxilla anesthesia needle. These four options are placed in separate envelopes in a package and placed in the first session of the intervention in front of the child and are randomly selected by the child and given to the practitioner and the intervention is performed. The second session is on the opposite side and the second method is done.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In this study the supervisor does the injection and during the injection the FLACC questionnaire is filled by the secretary who has no information about the dental work and the type of anesthesia, so this person is blind. Also, the student doing the restoration work (which is the same student working on this thesis) will be blind because he does not know in what way the child is numb.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

##### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of the Faculty of Dentistry, University of Tehran

##### Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

##### City

tehran

##### Province

Tehran

##### Postal code

1467664961

#### Approval date

2019-07-29, 1398/05/07

#### Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1398.085

#### Health conditions studied

##### 1

#### Description of health condition studied

Efficacy and acceptance of a new local anesthesia technique (needleless injection)

#### ICD-10 code

#### ICD-10 code description

#### Primary outcomes

##### 1

#### Description

The pain and discomfort questionnaire (FLACC) is rated as 3 (0 1 2) as to whether the condition (face / legs / child activity / crying during injection and child sympathy).

#### Timepoint

The FLACC questionnaire is filled in at the time of anesthesia injection and during the regenerative treatment.

#### Method of measurement

The pain and discomfort questionnaire (FLACC) is rated as 3 (0 1 2) as to whether the condition (face / legs / child activity / crying during injection and child sympathy).

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group is a group that is anesthetized with a needleless anesthesia. In this method, a compression anesthesia device called Madajet is used, which does not have a needle and can be sterilized. Milk Spray, which each time sprays 0.1 ml of anesthetic into a small area of tissue (the only area we want to anesthetize), which is lent to a needle because of its jet depth. Anesthesia is injected at three points: the mesococcal / distal buccal and palatal.

#### Category

Treatment - Devices

### 2

#### Description

Control group: Control group: There are groups that are anesthetized with the usual anesthetic. The usual injection of anesthesia with a needle is as follows: The anesthetic is injected with a sterile syringe and the needle (which is available in different gauges) is injected deep into the vestibule. Lidocaine anesthesia is 2% and epinephrine is 1 in 80,000 for the drug distribution company.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran university of medical sciences

##### Full name of responsible person

Ghazaleh Baniebrahimi

##### Street address

Khani Abadno - Shariati Town - Mahan Street -  
Opposite Shariati Park - International Campus Dental  
School

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Tehran

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1696617814

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr Ghazaleh Baniebrahimi

##### Street address

Faculty of Dentistry, Shahid Zolfi St. (Mahan), Tehran,  
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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

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Ghazaleh Baniebrahimi

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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Complex Golchin Laleh 60 Ave Laleh Alley Aqdessia  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is 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

Yes - There is 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

### Title and more details about the data/document

All potential data is shared after unidentifiable people.

### When the data will become available and for how long

Start of access period from 1399

### To whom data/document is available

All applicants

### Under which criteria data/document could be used

Can be used in all situations.

### From where data/document is obtainable

Tehran University of Medical Sciences

### What processes are involved for a request to access data/document

There is no specific process.

### Comments