

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity

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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 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 -
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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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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