

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the efficacy of infiltration with 4% articaine and 2% lidocaine for extraction of maxillary primary molars

Protocol summary

Study aim

Comparing the efficacy of infiltration with 4% articaine and 2% lidocaine for extraction of maxillary primary molars

Design

cross-over, double blinded, randomized clinical trials randomization is performed by block randomization method.

Settings and conduct

In this study, clinician who collects data and the child will be blinded to the anesthetic solution. In order to inject local anesthesia, the area is first dried by sterilized gauze and then the topical anesthetic gel containing benzocaine will be placed at the injection site for 1 minute. Then, for the buccal infiltration of one side, 1.5 ml of cartridge containing 2% lidocaine and 1:80000 epinephrine and for the other side (in the next session, 1 week later) 4% articaine and 1:100000 epinephrine will be used. The rest of the cartridge will be injected 2 mm above the lingual margin. 3 minutes after injection of both anesthesia, the sense of soft tissue is examined by the explorer in the buccal and lingual gingiva. Maximum waiting for anesthesia is 5 minutes. If soft tissue is not anesthetized, it is considered as a failure in the anesthesia and the tooth will be excluded from the study. After obtaining soft tissue anesthesia, the tooth will be loosed by elevator and in absence of complete anesthesia during luxation, the tooth will be excluded from the study. In order to evaluate the efficacy of anesthetic substance, we utilize facial analogue scale and after extraction, we show the scale to the child and he will mention the smiley most resemble his pain. It should be mentioned that informed consent will be obtained from parents before treatment procedure.

Participants/Inclusion and exclusion criteria

6 to 9 year old cooperative children needing 2 primary molars extraction

Intervention groups

intervention I: infiltration with 2% lidocaine intervention

II: infiltration with 4% articaine

Main outcome variables

pain during extraction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161029030552N2**

Registration date: **2018-12-24, 1397/10/03**

Registration timing: **retrospective**

Last update: **2018-12-24, 1397/10/03**

Update count: **0**

Registration date

2018-12-24, 1397/10/03

Registrant information

Name

yasamin khaksar

Name of organization / entity

shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 8091

Email address

khaksar_y@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2018-12-06, 1397/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of infiltration with 4% articaine and 2% lidocaine for extraction of maxillary primary molars

Public title

comparing the pain during extraction of maxillary primary molars after injection with articaine and lidocaine

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

at least 2 maxillary primary molars with same characteristics needing extraction cooperative behavior for dental treatment under local anesthesia physical and psychological health of the child

Exclusion criteria:

history of allergy to local anesthetic solution abscess in the injection site consumption of analgesics in the last 24 hours

Age

From **6 years** old to **9 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

More than 1 sample in each individual

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

2 maxillary primary molars

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization has been used. block size is 4 and a total number of 11 blocks is created.

Blinding (investigator's opinion)

Double blinded

Blinding description

as both injections use same method, the child is blinded to the treatment. the investigator help the child to scale the pain, enters the operation room after injection and is blinded to the local anesthetic agent.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of shiraz university of medical sciences

Street address

Karim khan zand Ave.,Central building of shiraz university of medical sciences

City

shiraz

Province

Fars

Postal code

71348-14336

Approval date

2018-12-19, 1397/09/28

Ethics committee reference number

IR.SUMS.REC.1397.802

Health conditions studied**1****Description of health condition studied**

local anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes**1****Description**

pain

Timepoint

during tooth extraction

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: infiltration with a carpule 2% lidocaine and 1.80000 epinephrine

Category

Prevention

2**Description**

Intervention group: infiltration with a carpule containing

4% articaine and 1.100000 epinephrine
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
private dental clinic
Full name of responsible person
Dr. Soleiman Fijan
Street address
Rahmatabad Ave., Pras complex
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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khaksar_y@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Yasamin Khaksar
Position
Assistant professor
Latest degree
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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data and the result of statistical analysis of the clinical trial

When the data will become available and for how long

1 year later

To whom data/document is available

Researchers

Under which criteria data/document could be used

after publication of the article

From where data/document is obtainable

sending Email to the researchers

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

Sending the request via the email

Comments