# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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

**City**

Shiraz

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**Postal code**

71346-153888

**Phone**

+98 71 3627 6615

**Email**

dr@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Basir Hashemi

**Street address**

Zand Ave

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**Province**

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**Postal code**

7195944315

**Phone**

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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**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**
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**Latest degree**
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**Email**
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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**
1year 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**