

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### A clinical trial to compare the effectiveness of buccal infiltration with 2% lidocaine versus 4% articaine in palatal anesthesia for maxillary teeth extraction

#### Protocol summary

##### Study aim

To compare the effectiveness of buccal infiltration with 2% lidocaine versus 4% articaine in palatal anesthesia for maxillary teeth extraction

##### Design

Totally, 300 patients in the Dental Clinic of Mashhad Faculty of Dentistry, Mashhad, Iran are selected in this study. In this double-blind, controlled clinical trial, the patients are assigned into parallel groups using simple random sampling methods.

##### Settings and conduct

Patients referring to the Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection and participant are blind to group allocation.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged range 16-60 years; requiring maxillary teeth extraction. Exclusion criteria: Having drug intolerance; pregnant women; having the uncontrolled systemic disease; mental retardation; having oral infections.

##### Intervention groups

Intervention group I will receive 0.6 mL of 2 % lidocaine with epinephrine 1:100000. Intervention group II will receive 0.6 ml of 4% articaine hydrochloride with epinephrine 1:100000.

##### Main outcome variables

Evaluation and comparison of the rate of palatal anesthesia in two intervention groups.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180710040413N1**

Registration date: **2020-11-15, 1399/08/25**

Registration timing: **prospective**

Last update: **2020-11-15, 1399/08/25**

Update count: **0**

##### Registration date

2020-11-15, 1399/08/25

##### Registrant information

###### Name

Ali Mohammadzadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 4722 0338

###### Email address

mohammadzadeha933@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-11-22, 1400/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial to compare the effectiveness of buccal infiltration with 2% lidocaine versus 4% articaine in palatal anesthesia for maxillary teeth extraction

**Public title**

The effectiveness of lidocaine and articaine in palatal anesthesia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Aged range 16-60 years Requiring maxillary teeth extraction

**Exclusion criteria:**

Having drug intolerance Pregnant women Having uncontrolled systemic disease Mental retardation Having oral infections

**Age**

From **16 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **300**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients referring to Dental Clinic of Mashhad Faculty of Dentistry, randomly base on random number table method and Randomizer.org website assigned two intervention groups. A code was allocated to each of the participants.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients referring to the Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection and participant are blind to group allocation.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9188611393

**Approval date**

2018-03-07, 1396/12/16

**Ethics committee reference number**

IR.MUMS.SD.REC.1394.311

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

Maxillary teeth extraction

**ICD-10 code**

K08.9

**ICD-10 code description**

Disorder of teeth and supporting structures, unspecified

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

Palatal anesthesia

**Timepoint**

every 2 minutes over 1 hour after intervention

**Method of measurement**

Based on the questionnaire

**Secondary outcomes**

empty

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

Intervention group: Intervention group I will receive 0.6 mL of 2 % lidocaine with epinephrine 1:100000.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: Intervention group II will receive 0.6 ml of 4% articaine hydrochloride with epinephrine 1:100000.

**Category**

Treatment - Drugs

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Mashhad Faculty of Dentistry Dental Clinic

**Full name of responsible person**

Ali Mohammadzade

**Street address**

Dental Clinic of Mashhad Faculty of Dentistry,  
Opposite Mellat Park, Vakilabad Blvd

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

+98 51 3883 2301

**Email**

j.m.dental.s@mums.ac.ir

**Web page address**

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Vice Chancellor for Research, Mashhad University of  
Medical Sciences, Ghoreishi building, Daneshgah  
Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

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**Email**

j.m.dental.s@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahdi Gholami

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Dental Clinic of Mashhad Faculty of Dentistry,  
Opposite Mellat Park, Vakilabad Blvd

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**Email**

gholamimh@mums.ac.ir

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahdi Gholami

**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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahdi Gholami

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**Email**

gholamimh@mums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

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**

Information on the main outcome or the like can be shared.

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

6 months after printing results

**To whom data/document is available**

Our data will only be available to researchers working at science centers and universities.

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

Our data will be available for scholars working at science centers and universities.

**From where data/document is obtainable**

Mahdi Gholami provides the data analysis to the applicants via email: gholamimh@mums.ac.ir

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

Applicants can respond to the email of the respondent and receive a response within a week.

**Comments**