

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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
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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

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

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Dental Clinic of Mashhad Faculty of Dentistry,
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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