

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative evaluation of anesthetic efficacy of 1.8 and 3.6 milliliter buccal infiltrations, and buccal plus palatal infiltrations with articaine in maxillary first molars with irreversible pulpitis

Protocol summary

Summary

Goal : To choose the best anesthetic administration technique for first maxillary molar diagnosed with irreversible pulpitis Study design : Randomized , single blind clinical trial Inclusion Criteria :Patients with first maxillary molar diagnosed with Symptomatic Irreversible Pulpitis Exclusion Criteria : patients that have used sedatives in the last 12 hours, pregnancy, allergies sample size :45 study intervention : Group 1:1.8 milliliters buccal infiltration Group 2 : 3.6 milliliters buccal infiltration , Group 3 : 1.8 milliliters buccal infiltration plus 0.5 milliliters palatal infiltration Intervention time : before access cavity preparation Outcomes Studied : level of pain on a visual analogue scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011020238N2**
Registration date: **2015-03-04, 1393/12/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-04, 1393/12/13

Registrant information

Name

Farzaneh Afkhami Jeddi

Name of organization / entity

Tehran University of Medical Sciences International Campus

Country

Iran (Islamic Republic of)

Phone

+98 21 5585 1131

Email address

f-afkhami@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences International Campus Dental School

Expected recruitment start date

2014-01-15, 1392/10/25

Expected recruitment end date

2015-03-15, 1393/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of anesthetic efficacy of 1.8 and 3.6 milliliter buccal infiltrations, and buccal plus palatal infiltrations with articaine in maxillary first molars with irreversible pulpitis

Public title

Comparison of anesthetic efficacy of articaine in different anesthetic administration methods and volumes in maxillary first molars

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: Patients with systemic diseases , Patients that have used any form of sedatives in the past 12 hours , Patients that have allergies to anesthetics or sulfites, pregnancy , Patients that are unable give informed consent , Patients with periapical lesions.
Inclusion criteria :Patients between the ages of 18 to 60 ,

Patients with first maxillary molars diagnosed with Symptomatic Irreversible Pulpitis

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences International
Campus Dental School

Street address

Zolfi St. - Khani Abad no

City

Tehran

Postal code

Approval date

2013-07-14, 1392/04/23

Ethics committee reference number

21092

Health conditions studied

1

Description of health condition studied

Irreversible Pulpitis

ICD-10 code

k04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Pain

Timepoint

after 20 minutes

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

group 1: Maxillary first molar buccal infiltration with 4%
Articaine with 1:100000 Epinephrine 1.8 ml

Category

Treatment - Other

2

Description

group 2 :Maxillary first molar buccal infiltration with 4%
Articaine with 1:100000 Epinephrine 3.6 ml

Category

Treatment - Other

3

Description

group 3:Maxillary first molar buccal infiltration with 4%
Articaine with 1:100000 Epinephrine 1.8 ml plus palatal
infiltration with 4% Articaine with 1:100000 Epinephrine
0.5 ml

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences International
Campus Dental School

Full name of responsible person

Reza Yazdani

Street address

Zolfi St. -Khani Abad no - Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences International
Campus Dentistry School

Full name of responsible person

Reza Yazdani

Street address

Zolfi St. -Khani Abad no - Tehran

City

Tehran

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 International
Campus Dentistry School

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences International
Campus Dentistry School

Full name of responsible person

Fardad Kamalian

Position

Professional Doctorate Student

Other areas of specialty/work

Street address

Zolfi St. - Khani Abad no

City

Tehran

Postal code

Phone

+98 21 5585 1149

Fax

Email

fardad.kamalian@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences International

Campus Dentistry School

Full name of responsible person

Farzane Afkhami Jeddi

Position

Endodontist , Assistant Professor

Other areas of specialty/work

Street address

Zolfi St. - Khani Abad no

City

Tehran

Postal code

Phone

+98 21 5585 1149

Fax

Email

f-afkhami@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences International
Campus Dentistry School

Full name of responsible person

Fardad Kamalian

Position

Professional Doctorate Student

Other areas of specialty/work

Street address

Zolfi St. - Khani Abad no

City

Tehran

Postal code

Phone

00

Fax

Email

fardad.kamalian@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty