

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Anaesthetic efficiency of supplemental infiltration of retromolar pad after inferior alveolar nerve block in mandibular first molars with symptomatic irreversible pulpitis.

Protocol summary

Study aim

Measuring the sufficiency of retromolar pad infiltration after inferior alveolar nerve block

Design

In this study 50 patients with spontaneous pain and irreversible pulpitis of mandibular first molar referring to dental university were chosen.

Settings and conduct

This study is doing in Shiraz Azad Dental University. Each patient get checked to be in our inclusion criteria, then inform consent will given.

Participants/Inclusion and exclusion criteria

Exclusion criteria: younger than 18 years, allergic to local anesthetics or sulfites, pregnancy, history of significant medical conditions, taking any medications like over-the-counter painkillers, sedatives, anti-anxiety or antidepressant medications that may affect pain assessment active sites of Pathosis in the area of injection and inability to give informed consent. Inclusion criteria: mandibular first molars with irreversible pulpitis and spontaneous pain.

Intervention groups

Injection of infiltration in retromolar pad

Main outcome variables

Numbness of mandibular first molar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161031030608N2**

Registration date: **2018-08-08, 1397/05/17**

Registration timing: **retrospective**

Last update: **2018-08-08, 1397/05/17**

Update count: **0**

Registration date

2018-08-08, 1397/05/17

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

Email address

karamifar@iaushiraz.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-16, 1396/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Anaesthetic efficiency of supplemental infiltration of retromolar pad after inferior alveolar nerve block in mandibular first molars with symptomatic irreversible pulpitis.

Public title

Effect of retromolar pad infiltration on mandibular first molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mandibular first molars with irreversible pulpitis
Spontaneous pain
Exclusion criteria:
younger than 18 years allergic to local anesthetics or sulfites pregnancy history of significant medical conditions taking any medications like over-the-counter painkillers, sedatives, anti-anxiety or antidepressant medications that may affect pain assessment active sites of Pathosis in the area of injection inability to give informed consent

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz Azad University

Street address

No. 14, South Ghaani st., Azad university of dentistry

City

shiraz

Province

Fars

Postal code

7473171987

Approval date

2018-07-02, 1397/04/11

Ethics committee reference number

IR.IAU.SHIRAZ.REC.1397.001

Health conditions studied

1

Description of health condition studied

Symptomatic irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Numbness or lack of numbness

Timepoint

15 and 5 minutes after injection

Method of measurement

Electric pulp tester and cold test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Administer of half of cartridge volume of 2% lidocaine with 1:100000 epinephrine in the retromolar pad area

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Azad dentistry university of shiraz

Full name of responsible person

Kasra Karamifar

Street address

No. 14, South Ghaani st., Azad university of dentistry

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Email

kasra.karamifar@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Tahereh Baheri Moghadam

Street address

No. 14, South Ghaani st., Azad dentistry university

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Fax

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Kasra karamifar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Position

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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Those part of documents that are related to main subject will be released after making the participants unknown.

When the data will become available and for how long

2 years after publishing the results.

To whom data/document is available

Dentists

Under which criteria data/document could be used

To make progress in this research and the do related studies,documents will be available.

From where data/document is obtainable

- 1.Dr. kasra karamifar(kasra.karamifar@gmail.com)
- 2.Dorna shirali(dorna.sh96@gmail.com)

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

Demander have to send us the reason that he or she needs the documents.

Comments