

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of 20% benzocaine gel on the pain caused by lower alveolar nerve block injections

Protocol summary

Study aim

Effect of 20% benzocaine gel on pain in inferior alveolar nerve block injections

Design

This study is a double blind clinical trial. Patients were randomly divided into two groups receiving 20% benzocaine gel as the intervention group and placebo gel receiving group (fluoride APF with the same taste and odor as benzocaine gel). After receiving these alveolar nerve block injections. Inferior. After the injection, the VAS scale is shown to the patient to indicate their pain level. The total sample size for each group (control and intervention) is equal to 58 samples.

Settings and conduct

This study is a double blind clinical trial. The study population was all patients referred to the Dental Clinic of Mazandaran University of Medical Sciences in 2018. The patients and surgeon are blinded.

Participants/Inclusion and exclusion criteria

The study population was all patients referred to the Dental Clinic of Mazandaran University of Medical Sciences in 2018 and the exclusion criteria were as follows: 1. Having a systemic illness in which the use of lidocaine anesthesia is partially or completely prohibited. 2. Existence of toothache The rest of patients who do not qualify for exclusion are included.

Intervention groups

Patients were randomly divided into two groups receiving 20% benzocaine gel as the intervention group and placebo gel receiving group (fluoride APF with the same taste and odor as benzocaine gel). After receiving these alveolar nerve block injections. Inferior. After the injection, the VAS scale is shown to the patient to indicate their pain level.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151017024573N8**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Mohadeseh Heidari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8351

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-16, 1398/06/25

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 20% benzocaine gel on the pain caused by lower alveolar nerve block injections

Public title

The effect of topical anesthesia on injection pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Indication of mandibular tooth extraction

Exclusion criteria:

Having a systemic disease in which the use of lidocaine anesthesia is partially or completely prohibited.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 58

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into intervention and control groups using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Application of placebo fluoride gel APF (master dent) with the same taste and odor as benzocaine gel

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Ethics committee of mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Science, Imam square, sari, Mazandaran

City

Sari

Province

Mazandaran

Postal code

4812685976

Approval date

2017-11-26, 1396/09/05

Ethics committee reference number

IR.MAZUMS..REC.1398.1181

Health conditions studied

1

Description of health condition studied

Extraction due to caries

ICD-10 code

k02.8

ICD-10 code description

Other dental caries

Primary outcomes

1

Description

Pain intensity

Timepoint

Before and after injection

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: topical anesthetic gel Benzocaine 20% (master-dent USA) put on a cotton swap as much as a pea after the area is dried with air.then it is applied for two minutes (recommended factory duration) in 5 to 10 mm of gingiva in the vestibule area where the 27 gauge needle is to be inserted.one cartridge of 2% lidocaine (daroopakhsh) is injected at the site within a minute.

Category

Treatment - Drugs

2

Description

Control group:oral fluoride (APF gel thixotropic)(master-dent USA) put on a cotton swap as much as a pea after the area is dried with air.then it is applied for two minutes (recommended factory duration) in 5 to 10 mm of gingiva in the vestibule area where the 27 gauge needle is to be inserted.one cartridge of 2% lidocaine (daroopakhsh) is injected at the site within a minute.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran University of Medical Science, Sari Dental Faculty

Full name of responsible person

Mohadeseh Heidari

Street address

Faculty of Dentistry, University of Medical Sciences, near Tooba clinic, Khazar Square, Sari, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran university of Medical Science

Full name of responsible person

Farhad Sobouti

Street address

Faculty of Dentistry, University of Medical Sciences, near Tooba clinic, Khazar Square, Sari, Iran

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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

Mazandaran university of Medical Science

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

Tehran University of Medical Sciences

Full name of responsible person

Mohadeseh Heidari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Tehran University of Medical Sciences, Dental Implant Research Center, Ghods Street, Enghelab Av, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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