Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 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

Email address
mheidari@mazums.ac.ir

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

City
Sari

Province
Mazandaran

Postal code
4816895476

Phone
+98 11 3565 5939

Email
heidari_mohadeseh@yahoo.com

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

City
Sari

Province
Mazandaran

Postal code
4816895477

Phone
+98 11 3325 4135

Email
farhad_sobouti@yahoo.com

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

City
Tehran

Province
Tehran

Postal code
4816895477

Phone
+98 21 8897 8351

Fax

Email
mheidari@mazums.ac.ir

Person responsible for scientific 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
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Phone
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Fax

Email
mheidari@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

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Mohadeseh Heidari

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Fax

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mheidari@mazums.ac.ir

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