Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of anesthetic solution temperature effect on success of pulpal anesthesia following inferior alveolar nerve block injection in teeth with symptomatic irreversible pulpitis

Protocol summary

Study aim

Determination of the effect of anesthetic solution temperature on the success of pulpal anesthesia due to injection of inferior alveolar nerve block in teeth with symptomatic irreversible pulpitis

Design

The clinical trial consisted of three intervention groups, with parallel, single-blind, randomized groups. Excel software rand function is used for randomization.

Settings and conduct

This study is performed in the field of dental treatment in Bojnourd Dental School. 60 patients are randomly divided into three groups and each group receives anesthesia solution at one of the temperatures of 4, 20 and 37 ° C as a inferior alveolar nerve block. Prior to the injection, cold and electrical tests are taken from the tooth to make sure the tooth is vital. 15 minutes after the injection, cold, electrical and VAS tests are taken from the patient and the success of anesthesia is evaluated.

Participants/Inclusion and exclusion criteria

No entry condition: Alcohol or drug addiction or smoking Taking psychiatric drugs Has a systemic disease affecting the dental treatment plan Patients taking painkillers on the day of injection Has calcification in the pulp and canal of the desired tooth Patients who do not show signs of onset of lip anesthesia with a single inferior nerve block injection History of dentoalveolar trauma Entry condition: Presence of mandibular molars with irreversible pulpitis Adults over 18 years Patient permission

Intervention groups

Patients are randomly divided into three groups and in each group receive an inferior alveolar nerve block injection with one of the temperatures of 4, 20 and 37 ° C.

Main outcome variables

pulpal anesthesia response to cold test response to heat test response to electrical test verbal analogue scale age sex

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201109049322N1**
Registration date: **2020-12-18, 1399/09/28**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-18, 1399/09/28**
Update count: **0**

Registration date

2020-12-18, 1399/09/28

Registrant information

Name

Ali Farahnejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-16, 1399/08/26

Expected recruitment end date

2021-02-14, 1399/11/26

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of anesthetic solution temperature effect on success of pulpal anesthesia following inferior alveolar nerve block injection in teeth with symptomatic irreversible pulpitis

Public title
Clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence a mandibular molar with symptomatic irreversible pulpitis Adults over 18 years old Patient permission
Exclusion criteria:
Patients who are alcohol or drug addicted or smoking Patients who are taking psychiatric drugs Patients who have a systemic disease affecting the dental treatment plan Patients who are taking painkillers on the day of injection Teeth which have calcification in the pulp and canal of the desired tooth Patients with history of dentoalveolar trauma Patients who do not have any symptom of lip numbness after a single inferior nerve block injection
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Balanced (permuted) block randomization (For example, if a, b, and c are our three groups, they are divided this way: baccab, cbbaca, ...)
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants and data analyzers were kept blind in the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Bojnurd university of medical sciences
Street address
The central building of North Khorasan University of Medical Sciences, Dolat Blvd.
City
Bojnurd
Province
North Khorasan
Postal code
7487794149
Approval date
2020-11-01, 1399/08/11
Ethics committee reference number
IR.NKUMS.REC.1399.069

Health conditions studied

1

Description of health condition studied
Inferior alveolar nerve block anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Response to the electrical test
Timepoint
Before anesthesia injection - 15 minutes after anesthesia injection - 1 minute after the last test
Method of measurement
via electrical pulp tester

2

Description
Response to the cold test
Timepoint
Before anesthesia injection - 15 minutes after anesthesia injection - 1 minute after the last test
Method of measurement
Based on the standard cold test method for dental vitality testing

3

Description
Response to the Verbal Analog Scale
Timepoint
When preparing the access cavity
Method of measurement
Based on the patient's verbal response

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Anesthesia injection at a temperature of 37 ° C
Category
Treatment - Devices

2

Description
Intervention group: Anesthesia injection at a temperature of 4 ° C
Category
Treatment - Devices

3

Description
Control group: Anesthesia injection at a temperature of 20 ° C
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized clinic of Bojnourd Dental School
Full name of responsible person
Mahsa Dastpak
Street address
School of Dentistry, Near Imam Hassan Hospital, Arkan Road
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http://nkums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Dr. Kaveh Hojjat
Street address
Shahriar St., above Imam Ali Hospital, School of Medicine, Vice Chancellor for Research and Technology
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Web page address
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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
Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
Mahsa Dastpak
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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Student

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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

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