

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 51 3893 7010

##### Email address

afnphenomenon@gmail.com

##### 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

##### City

Bojnurd

##### Province

North Khorasan

##### Postal code

94176-94735

##### Phone

+98 58 3229 6764

##### Email

INFO@NKUMS.AC.IR

##### Web page address

<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

#### City

Bojnurd

#### Province

North Khorasan

#### Postal code

74877-94149

#### Phone

+98 58 3229 6764

#### Fax

#### Email

INFO@NKUMS.AC.IR

#### Web page address

<http://nkums.ac.ir/>

#### 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

##### Street address

Faculty of Dentistry, south side of Imam Ali Hospital, Shahriar St.

##### City

Bojnurd

##### Province

North Khorasan

##### Postal code

9417694735

##### Phone

+98 58 3229 6764

**Email**

mahsa.dastpak@yahoo.com

**Person responsible for scientific 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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**Email**

mahsa.dastpak@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Ali Farahnejad

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

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afnphenomenon@gmail.com

**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