

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of mental nerve block with pressure along with inferior alveolar nerve block on root canal treatment of mandibular first molars with asymptomatic irreversible pulpitis: a triple blind randomized clinical trial

#### Protocol summary

##### Summary

Study aim: evaluation of the effect of mental nerve block(MNB) with pressure following inferior alveolar nerve block (IANB) on anesthetic success of first mandibular molars with asymptomatic irreversible pulpitis. Study design: clinical trial, randomized, triple blind, non-controlled with placebo, single center, phase 3 of trial. Table of random numbers is used for randomization in this study. Target population of the study: patients referring to Endodontics Department of Tabriz Dental Faculty for root canal treatment in 2016-2017. Main inclusion criteria: mandibular first molars with asymptomatic irreversible pulpitis and normal periapical radiography appearance without sensitivity to percussion. Exclusion criteria: patients with tooth pain at the time of study. Sample size is 70(35 per group). Interventions of this study: In both groups, after injection of a standard IANB using 1.8 ml 2% lidocaine with 1:100000 epinephrine, a standard MNB including 1.8 ml 2% lidocaine with 1:100000 epinephrine will be given by an operator not involved in assessing the outcomes. After injection, in group 1(active treatment) the patient will apply firm fingers pressure on the soft tissue of mental foramen region for 1 minute with opposite hand and in group 2 (control treatment) the pressure will be applied on the crowns of premolar teeth. Primary outcome: Degree of electric pulp tester response (before and after intervention)

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016090329671N1**  
Registration date: **2016-10-21, 1395/07/30**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-10-21, 1395/07/30

##### Registrant information

###### Name

Amir Ardalan Abdollahi

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor of Research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2017-03-19, 1395/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of mental nerve block with pressure along with inferior alveolar nerve block on root canal treatment of mandibular first molars with asymptomatic irreversible

pulpitis: a triple blind randomized clinical trial

## Public title

Anesthesia efficiency of mental nerve block with pressure along with inferior alveolar nerve block

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Healthy adults aged from 18 to 55 years; mandibular first molars with asymptomatic irreversible pulpitis and normal periapical radiography appearance without sensitivity to percussion. Clinical diagnosis of tooth with irreversible pulpitis will be confirmed by positive response to electric pulp tester (PARKELL, PT-20, USA) and a lingering exaggerated response (>10 seconds) with moderate-to-severe pain to cold test after the cotton pellet removal. Exclusion criteria: systemic disease; patients with tooth pain at the time of study; unstable heart disease; known allergy to local anesthetic agents of lidocaine 2% with 1/80000 epinephrine or latex; patients taking sedatives; oral/facial paresthesia; use of analgesics and anxiety medications for 12 hours before the treatment or any other drugs; symptomatic irreversible pulpitis cases; presence of periapical radiolucency; pregnancy; breast-feeding; non-repairable tooth and presence of crown.

## Age

From **18 years** old to **55 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Table of random numbers is used for randomization in this study

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

## Street address

Tabriz University of Medical Sciences, Daneshgah Avenue, Tabriz

## City

Tabriz

## Postal code

## Approval date

2016-07-25, 1395/05/04

## Ethics committee reference number

IR.TBZMED.REC.1395.485

## Health conditions studied

### 1

#### Description of health condition studied

local anesthesia

#### ICD-10 code

-

#### ICD-10 code description

-

## Primary outcomes

### 1

#### Description

degree of electric pulp tester response

#### Timepoint

before and after local anesthesia injection

#### Method of measurement

Electric pulp tester(EPT)

## Secondary outcomes

### 1

#### Description

pain intensity

#### Timepoint

During initial stages of root canal treatment(access cavity preparations)

#### Method of measurement

visual analoge scale

## Intervention groups

### 1

#### Description

In both groups, after injection of a standard inferior alveolar nerve block using 1.8 ml 2% lidocaine with 1:100000 epinephrine, a standard mental nerve block including 1.8 ml 2% lidocaine with 1:100000 epinephrine will be given within 60 seconds by an operator not involved in assessing the outcomes. After injection, in group 1(active treatment) the patient will apply firm fingers pressure on the soft tissue of mental foramen region for 1 minute with opposite hand.

#### Category

Treatment - Drugs

**2**

**Description**

In both groups, after injection of a standard inferior alveolar nerve block using 1.8 ml 2% lidocaine with 1:100000 epinephrine, a standard mental nerve block including 1.8 ml 2% lidocaine with 1:100000 epinephrine will be given within 60 seconds by an operator not involved in assessing the outcomes. After injection, in group 2 (control treatment) the patient will apply the pressure on the crowns of premolar teeth for 1 minute with opposite hand.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Department of Endodontics, Dental faculty

**Full name of responsible person**

Dr. Shahriar Shahi, Endodontist, Professor

**Street address**

Second floor, Entry 3, Dental Faculty, Daneshgah Avenue, Tabriz

**City**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor of Research, Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Samiei

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Second floor, Entry number 2, Tabriz dental faculty, Daneshgah Avenue, Tabriz

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Tabriz

**Grant name**

-

**Grant code / Reference number**

-

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor of Research, Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*