

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

Name of organization / entity

Department of Endodontics, Faculty of Dentistry, Tabriz University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3330 8174

Email address

samieim@tbzmed.ac.ir

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

Tabriz

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

Street address

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

City

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

Name of organization / entity

Department of Endodontics, Faculty of Dentistry

Full name of responsible person

Amir Ardalan Abdollahi

Position

Postgraduate student of Endodontics, Dentist

Other areas of specialty/work

Street address

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

City

Tabriz

Postal code

5166614711

Phone

+98 41 3330 8174

Fax

+98 41 3334 6977

Email

ardalan_2000a@yahoo.com;
abdollahiardalan@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Endodontics, Dental faculty

Full name of responsible person

Dr. Mohammad Samiei

Position

Endodontics, Associate professor

Other areas of specialty/work

Street address

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

City

Tabriz

Postal code

5166614711

Phone

+98 41333559659

Fax

+98 41 3334 6977

Email

samiei.mohAgmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Endodontics, Faculty of Dentistry

Full name of responsible person

Amir Ardalan Abdollahi

Position

Postgraduate student of Endodontics, Dentist

Other areas of specialty/work**Street address**

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

City

Tabriz

Postal code

5166614711

Phone

+98 413308174

Fax

+98 41 3334 6977

Email

ardalan_2000a@yahoo.com;
abdollahiardalan@gmail.com

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