Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation of the Anesthetic Efficacy of Intraosseous Anesthesia By Quicksleeper 5 computer-controlled system Versus inferior alveolar nerve Block in first Mandibular Molars with Irreversible Pulpitis.

Protocol summary

Study aim

Our aim is to evaluate the anesthetic efficacy of intraosseous anesthesia by Quicksleeper 5 computer controlled system versus inferior alveolar nerve block in first mandibular molars with irreversible pulpitis.

Design

In this clinical trial, 64 patients (32 males and 32 females) will participate and randomly receive one of two methods of anesthesia. Then the data will be divided into four groups based on age and anesthesia, the study is not blind

Settings and conduct

In this study, one of two different methods of anesthesia for patients who refer to the Department of Endodontics at Shahid Beheshti Dentistry School will be performed. The operator (anesthetic injector) is one endodontist and different from the researcher; according to the limitations, only the statistical analyst will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: between 18 and 60 years old; patient satisfaction to enter the study; patients should have at least one first vital mandibular molar without spontaneous pain; the absence of periapical radiolucency or any periapical lesions in radiography; patients without any systemic diseases; absence of acute inflammation and advanced periodontal disease at the first mandibular molar and adjacent Molar and premolar teeth and injection area. Exclusion criteria: lactate or pregnant women; any history of alergy to anesthetic solutions; using analgesic drugs since 12 hours before the treatment; severe dental pain that needs emergency treatment; non vital coronal pulp tissue; teeth with full crown; no pulp exposure after removing caries.

Intervention groups

For patients in two age groups (18 to 40 and 40 to 60 years old), anesthesia is performed randomly (intraosseous injection by Quicksleeper 5 and inferior alveolar nerve block).

Main outcome variables

Success of the anesthesia; onset and duration of anesthesia; pain; pulse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180930041187N1**
Registration date: **2019-02-05, 1397/11/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-05, 1397/11/16**
Update count: **0**

Registration date

2019-02-05, 1397/11/16

Registrant information

Name

Saeed Gharibian bejestani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Anesthetic Efficacy of Intraosseous Anesthesia By Quicksleeper 5 computer-controlled system Versus inferior alveolar nerve Block in first Mandibular Molars with Irreversible Pulpitis.

Public title

Comparison of two methods of intraosseous injection and lower alveolar nerve block in the first mandibular molars with irreversible pulpitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the patient is over 18 years and under the age of 60 years Patient Satisfaction to enter the study Patients have the ability to read and understand the consent and sign it Patients should have at least one first vital mandibular molar without spontaneous pain and positive response to Electrical Pulp Tester and prolonged response to the cold test The absence of periapical radiolucency or any periapical lesions in radiography Patients without any systemic diseases Absence of acute inflammation and advanced periodontal disease at the first mandibular molar and adjacent Molar and premolar teeth and injection area

Exclusion criteria:

History of any cardiovascular disease and high blood pressure Lactate or pregnant women Any history of alergy to anesthetic solutions Using analgesic drugs since 12 hours before the treatment Mobility more than 0.5 mm Probing more than 3 mm in mesial and distal Severe dental pain that needs emergency treatment Non vital coronal pulp tissue Teeth with full crown No lip numbness after the Inferior Alveolar Nerve Block injection No pulp exposure after removing caries lack of cooperation or interest of patient to continue the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals after obtaining consent to participate in this research are divided by stratified balanced block randomization method Into four groups (A, B, C and D) with 16 people in every group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Dental Research Institute, Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Dental School, Daneshjoo boulevard, Shahriari square, Velenjak

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Postal code

1983963113

Approval date

2017-08-01, 1396/05/10

Ethics committee reference number

IR.SBMU.RIDS.REC.1396.504

Health conditions studied

1

Description of health condition studied

Asymptomatic irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Asymptomatic irreversible pulpitis

Primary outcomes

1

Description

Success of the Anesthesia

Timepoint

After the Injection and during root canal therapy (RCT)

Method of measurement

Vitality pulp test (Electrical pulp tester and endo ice) before RCT and questioning from patients during RCT

2

Description

Pain during injection

Timepoint

During injection of Anesthetic solution and immediately

after completion of injection

Method of measurement

Heft-parker visual Analogue Scale

3

Description

Pain

Timepoint

Before injection (during vital pulp tests), after injection (during the evaluation of anesthesia success)

Method of measurement

Heft-parker visual Analogue Scale

4

Description

Pulse

Timepoint

Before injection , after injection

Method of measurement

Pulse-oximeter

5

Description

Onset of Anesthesia

Timepoint

After the injection with 1-minute intervals for a period of 15 minutes

Method of measurement

Vitality pulp test (pulp tester and endo ice)

6

Description

Duration of Anesthesia

Timepoint

From the beginning to the end of the treatment session

Method of measurement

Asking from the patients

Secondary outcomes

1

Description

anxiety

Timepoint

Before injection

Method of measurement

Visual Analogue Scale for Anxiety

Intervention groups

1

Description

Intervention group: For the first group (18 to 40 years old), Intraosseous injection technique would be used to achieve primary pulpal anesthesia using a QuickSleeper 5 device product by (Dental Hi Tec).

Category

Treatment - Other

2

Description

Intervention group: For the second group (40 to 60 years old), Intraosseous injection technique would be used to achieve primary pulpal anesthesia using a QuickSleeper 5 device product by (Dental Hi Tec).

Category

Treatment - Other

3

Description

Intervention group: For the third group (18 to 40 years old), inferior alveolar nerve block technique (conventional technique) would be used to achieve primary pulpal anesthesia.

Category

Treatment - Other

4

Description

Intervention group: For the fourth group (40 to 60 years old), inferior alveolar nerve block technique (conventional technique) would be used to achieve primary pulpal anesthesia.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeed Gharibian Bajestani

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Student Researcher
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified individual Participant Data.

When the data will become available and for how long

Starting 3 months after publication

To whom data/document is available

Available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

There is no limitation for what types of analyses will be used.

From where data/document is obtainable

Saeed Gharibian / saeed.gharibian@gmail.com / 00989120236300

What processes are involved for a request to access data/document

The applicant sends a request by sending an e-mail to the above-mentioned email; after reviewing his/her request, the data file will be sent to him/her within a maximum of one month.

Comments