

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of success of inferior alveolar nerve block in irreversible pulpitis teeth in supine and upright positions: A clinical study

Protocol summary

2020-12-27, 1399/10/07

Study aim

Comparison between the success inferior alveolar nerve block and teeth with irreversible pulpitis in both supine and upright positions.

Design

A clinical trial with two groups of nerve block in the upright and supine positions.

Settings and conduct

Center of School of Dentistry, Yazd Shahid Sadoughi University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: -Spontaneous & persistent pain in only one mandibular molar with caries. -Persistent response to cold test. -Class I & II medical histories. Exclusion Criteria: -Patients with a history of allergy to anesthetics. -Pregnant & breastfeeding patients. -Patients with pain in more than one tooth. -Patients with limited mobility or motor activity. -Patients with a previous history of or suspicious of drug abuse.

Intervention groups

Supine Group Upright Group

Main outcome variables

The results of this study can be used to inform about the application of inferior alveolar nerve block technique in a better position.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049528N1**

Registration date: **2020-12-27, 1399/10/07**

Registration timing: **retrospective**

Last update: **2020-12-27, 1399/10/07**

Update count: **0**

Registration date

Registrant information

Name

Nooshin Fakhari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3834 1804

Email address

nooshin_67@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-03, 1399/09/13

Expected recruitment end date

2020-12-13, 1399/09/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of success of inferior alveolar nerve block in irreversible pulpitis teeth in supine and upright positions: A clinical study

Public title

Comparison of success of inferior alveolar nerve block in irreversible pulpitis teeth in supine and upright positions: A clinical study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Spontaneous and persistent pain in only one of the molar

teeth with caries so that the tooth responds to the persistent cold test Medical Histories Class I and Class II Based on the American Society of Anesthesiology

Exclusion criteria:

Patients with a history of allergies Pregnant & breastfeeding patients Patients with pain in more than one tooth Patients with a history of or suspected with any drug abuse Patients with problems in the spine and neck Taking any medication that interferes with a person's perception of pain Any systemic condition that is a contraindication to inferior alveolar nerve block

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected from the qualified statistical population using simple sampling or convenient sampling method. Then, the samples will be assigned into the two intervention and control groups randomly; In so doing, 60 questionnaires will be prepared and labeled as A (30 questionnaires) and B (30 questionnaires); then, at the place of intervention, we will want the patient or his or her companion to choose one of them while he or she is blind about the type of treatment or group (blindness). Finally, we will have 30 patients in each group who are selected randomly.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding will be performed on patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

School of Dentistry, Shahid Sadoughi University of Medical Sciences, Imam Reza Square, Yazd, Iran, I. R.

ofe

City

Yazd

Province

Yazd

Postal code

8914815698

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

IR.SSU.REC.1398.216

Health conditions studied

1

Description of health condition studied

Inferior alveolar nerve block

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Success of anesthesia (block).

Timepoint

15 min

Method of measurement

local anesthesia of commissure (canthus) of the lips

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention Group: Upright Group: In this study, there are two groups of patients who will go to Yazd dental centers for the treatment of mandibular root canal for whom the diagnosis of irreversible pulpitis has been made. In one group of anesthesia, the inferior alveolar nerve block (IAN) will be injected by upright method and in the second group, this anesthesia will be performed by supine method. The choice of injection for these two groups will be random. The injection will be done with two carpules of 2% lidocaine with epinephrine 1/80000 (Iran Pharmaceutical Company). In the upright method, dental chair headrest has a 75-degree angle with the ground and the occlusal plane of the mandibular teeth is parallel to the ground, and during this injection, the practitioner will stand. The success of IAN block will be compared to measuring the numbness of the corner of the lip within 15 minutes after injection. The presence or absence of pain during the preparation of the access cavity will also be compared.

Category

Treatment - Drugs

2

Description

Second Intervention Group: Supine Group: In this study, there are two groups of patients who will go to Yazd dental centers for the treatment of mandibular root canal for whom the diagnosis of irreversible pulpitis has been Established. In one anesthesia group, the inferior alveolar nerve block (IAN) will be injected using the upright method and in the second group, the anesthetic will be injected using the supine method. The choice of injection for these two groups will be random. The injection will be done with two carpules of 2% lidocaine with epinephrine 1/80000 (Iran Pharmaceutical Company). In the supine group, the headrest of dental chair is lowered so that the patient's foot is a bit above the head and the patient's body is parallel to the floor. The practitioner will sit during this injection. The success of IAN block will be compared to measuring the numbness of the corner of the lip within 15 minutes after injection. The presence or absence of pain during the preparation of the access cavity will also be compared.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd dental centers

Full name of responsible person

Nooshin Fakhari

Street address

School of Dentistry, Shahid Sadoughi University of Medical Sciences, Imam Reza Square, Yazd, Iran, I. R. of

City

Yazd

Province

Yazd

Postal code

8914815698

Phone

+98 35 3621 3870

Email

Nooshin_67@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Nooshin Fakhari

Street address

School of Dentistry, Shahid Sadoughi University of Medical Sciences, Imam Reza Square, Yazd, Iran, I. R. of

City

Yazd

Province

Yazd

Postal code

8914815698

Phone

+98 35 3621 3870

Email

Nooshin_67@ymail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Nooshin Fakhari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Shahid Sadoughi University of Medical Sciences, Imam Reza Square, Yazd, Iran, I. R. of

City

Yazd

Province

Yazd

Postal code

8914815698

Phone

+98 35 3621 3870

Email

Nooshin_67@ymail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Nooshin Fakhari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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School of Dentistry, Shahid Sadoughi University of
Medical Sciences, Imam Reza Square, Yazd, Iran, I. R.
of

City

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Province

Yazd

Postal code

8914815698

Phone

+98 35 3621 3870

Email

Nooshin_67@ymail.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Nooshin Fakhari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Shahid Sadoughi University of
Medical Sciences, Imam Reza Square, Yazd, Iran, I. R.
of

City

Yazd

Province

Yazd

Postal code

8914815698

Phone

+98 21 8670 5503

Email

Nooshin_67@ymail.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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available