Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of fentanyl on the success of inferior alveolar nerve block for teeth with symptomatic irreversible pulpitis

Protocol summary

Study aim

The purpose of this study is to compare the success rate of inferior alveolar nerve block (IANB) injection carried out with two cartridges of 2% lidocaine with 1:100000 epinephrine each combined with 0.25 ml fentanyl versus two cartridges of 2% lidocaine with 1:100000 epinephrine each combined with 0.25 ml sterile distilled water for endodontic treatment of mandibular molars with symptomatic irreversible pulpitis.

Design

Randomised, double-blinded clinical trial with a parallel group design of 100 patients randomly divided into two groups of 50 subjects each, using random number generator software.

Settings and conduct

Department of Endodontics, Dental School, Isfahan Each random number will be kept in a separate sealed opaque envelope. This procedure is done by a third person who has no clue and has not involved in the rest of the study and only the random number is used on the data collection sheets to further blind the experiment.

Participants/Inclusion and exclusion criteria

One hundred adult patients will participate in this clinical trial. All of the subjects must be in good health as determined by a health history and oral questioning. Exclusion criteria were as follows: Under 18 years of age, allergy to local anesthetics or sulfites and the inability to give written informed consent or understand the use of pain scales. Also patients with a periapical lesion will not include in this study. Therefore, to qualify for the study, each patient must have a vital mandibular molar tooth with a clinical diagnosis of symptomatic irreversible pulpitis.

Intervention groups

Intervention group: 2 cartridges of 1.8 mL of 2% lidocaine with epinephrine each combined with 0.25 ml Fentanyl being injected. Control group: 2 cartridges of 1.8 mL of 2% lidocaine with epinephrine each combined with 0.25 ml sterile distilled water being injected.

Main outcome variables

Pain

General information

Reason for update

Acronym

مطالعه بی حسی دندان و فنتانیل اصفهان

IRCT registration information

IRCT registration number: **IRCT20191114045442N1**
Registration date: **2020-02-27, 1398/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-27, 1398/12/08**
Update count: **0**

Registration date

2020-02-27, 1398/12/08

Registrant information

Name
Neda Shekarchizade esfahani
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of fentanyl on the success of inferior alveolar nerve block for teeth with symptomatic irreversible pulpitis

Public title

Effect of fentanyl on the success of anesthesia for painful teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 years of age up to 60 in good health(ASA I (classification of the American Society of Anesthesiologists)) having at least one mandibular molar tooth with irreversible pulpitis Normal periapical radiographic appearance (except for a widened periodontal ligament) Not having severe periodontal problem No history of allergy to local anesthesia or sulfite

Exclusion criteria:

Taking any medications that might cause altered pain sensation Any swelling or sinus tract near the target tooth pregnant or nursing mothers Active sites of pathosis in the area of injection Inability of the patient to give an informed consent Lack of lip numbness within 15 minutes after injection

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization is based on block randomization using four blocks. 25 blocks of four quadrants will be selected randomly adopting random number table method. Patients under study will be assigned to one of two groups of intervention and control groups based on the order of blocks selection.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs used in similar cartridges are prepared. The mentioned drugs will be differentiated from each other based on a four-digit code that is pasted on them with the usage of a random number table method. There is no difference in terms of shape, size and other physical characteristics.Therefore, the patient and the individual assessing the impact of the intervention will not be able to detect the drug in the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran.

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81744-73461

Approval date

2019-10-08, 1398/07/16

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.430

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Pain

Timepoint

Before treatment and after initiating root canal therapy

Method of measurement

Heft-Parker visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 2 cartridges of 1.8 mL of 2% lidocaine with epinephrine each combined with 0.25 ml fentanyl applied by using conventional inferior alveolar nerve block injection technique.
Category
Treatment - Drugs

2

Description
Control group: 2 cartridges of 1.8 mL of 2% lidocaine with epinephrine each combined with 0.25 ml sterile distilled water applied by using conventional inferior alveolar nerve block injection technique.
Category
Placebo

Recruitment centers

1

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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?
Yes
Title of funding source
Esfahan 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

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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