

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Investigation of the Effect of topical application of amitriptyline and nortriptyline on irreversible pulpitis pain in teeth with failed pulpal anesthesia after a successful inferior alveolar nerve block

Protocol summary

Study aim

Determining the local effect of amitriptyline and nortriptyline drugs on teeth with irreversible pulpitis in which the successful injection of mandibular block anesthesia did not cause pulpal anesthesia.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized on 45 patients, random number table were used for randomization.

Settings and conduct

This study was done at the Endodontics Department of School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients requiring endodontic treatment of mandibular first molars showing the signs and symptoms of irreversible pulpitis and required treatment. Who had evidence of successful IAN block. Exclusion criteria: History of hypersensitivity to TCAs, lidocaine or epinephrine, Lack of Systemic diseases, Pregnancy and nursing mothers, Patients who took systemic analgesics within 4-6 hours prior to dental visit, Patients with complete anesthesia and no pain. The age of 10-68 years.

Intervention groups

Intervention group 1: Amitriptyline intervention
Intervention group 2: Nortriptyline intervention
Control group: starch powder as the placebo.

Main outcome variables

The main variable is pulpitis pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230313057710N1**

Registration date: **2023-04-27, 1402/02/07**

Registration timing: **retrospective**

Last update: **2023-04-27, 1402/02/07**

Update count: **0**

Registration date

2023-04-27, 1402/02/07

Registrant information

Name

Zahra Khosravani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-13, 1398/04/22

Expected recruitment end date

2019-12-28, 1398/10/07

Actual recruitment start date

2019-07-13, 1398/04/22

Actual recruitment end date

2019-12-28, 1398/10/07

Trial completion date

2019-12-28, 1398/10/07

Scientific title

Investigation of the Effect of topical application of amitriptyline and nortriptyline on irreversible pulpitis pain in teeth with failed pulpal anesthesia after a successful inferior alveolar nerve block

Public title

Investigation of the Effect of topical application of amitriptyline and nortriptyline on irreversible pulpitis pain in teeth with failed pulpal anesthesia after a successful inferior alveolar nerve block

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients requiring endodontic treatment of mandibular first molars showing the signs and symptoms of irreversible pulpitis and required treatment. Who had evidence of successful IAN block. Age 10-68 years

Exclusion criteria:

History of hypersensitivity to TCAs, lidocaine or epinephrine Lack of Systemic diseases (In according to self-report) Pregnancy and nursing mothers Patients who took systemic analgesics within 4-6 hours prior to dental visit, Patients with complete anesthesia and no pain.

Age

From **10 years** old to **68 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient will allocated a code and the patients assigned to three groups of 15 using a table of random numbers. In this way, intervention group 1 was assigned a two-digit code from 01 to 15, intervention group 2 was assigned a two-digit code from 16 to 30, and the control group was assigned a code from 31 to 45. Then, a number was randomly selected from the table of random numbers by placing a finger on it, and from the beginning of the selected number, the numbers were read in pairs in order. The numbers above 45 were removed, but the numbers between 01 and 45 were placed in one of 3 groups depending on the initial code assigned to each person in each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both patients and the dentist (researcher) were blind to the tube contents (double-blind design). Each Eppendorf tube was coded such that the dentist did not aware of its content. A coded Eppendorf tube was assigned to each patient by someone not involved in the study. After measuring the level of pain of patient during access cavity preparation and prior to pulp exposure, one Eppendorf tube randomly was assigned to each patient while the dentist did not aware of type of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The ethics committee of Isfahan University of Medical Sciences

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Hazar Jarib Ave, Isfahan University of Medical Sciences, Faculty of Dentistry, Isfahan, Iran

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Approval date

2019-06-26, 1398/04/05

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.204

Health conditions studied**1****Description of health condition studied**

Pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes**1****Description**

[The outcome variable is Irreversible pulpitis.

Timepoint

Pain will measure three times including: prior to the treatment onset, after the injection of anesthetic agent and initiation of access cavity preparation as the patient felt pain for the first time, and also after the application of medication

Method of measurement

McGill Visual Analogue Scale, Wong-Baker figure scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The diagnosis of irreversible pulpitis was confirmed by the heat and cold tests and presence of signs and symptoms of irreversible pulpitis such as severe long-lasting pain response to cold test, and pain during access cavity preparation (prior to pulp exposure). Patients showed signs of successful anesthetic injection 15 minutes after the IAN block injection of 2% lidocaine and 1:80,000 epinephrine (Darupakhsh Company, Tehran, Iran). 10 mg of amitriptyline (daroupakhsh company, Tehran, Iran) was prescribed. The colored coating of the tablets was removed and each tablet was powdered and mixed with 2 cc saline in an Eppendorf tube until a homogenous solution was obtained. The tubes were coded such that the dentist was blinded to the contents of each tube. The tube content was applied on exposed dentin by a microbrush, and a cotton pellet was placed over it, followed by a cotton roll and then the patient was requested to bite on it for 3 minutes. After this time period, the dentist continued the process of access cavity preparation and the pain score was measured again. Pain was measured three times prior to the treatment onset, after the injection of anesthetic agent and initiation of access cavity preparation as the patient felt pain for the first time, and also after the application of medication using the McGill visual analog scale (VAS) and Wong-Baker Faces Pain Rating Scale (PRS)

Category

Treatment - Drugs

2

Description

Intervention group 2: 10 mg of Nortriptyline (Sobhan darou company, Tehran, Iran) was prescribed. The method of prescribing, intervention and data measurement were the same as the intervention 1.

Category

Treatment - Drugs

3

Description

Control group: Placebo including 10 mg starch was prescribed. The method of prescribing, intervention and data measurement were the same as the first intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontics Department of Schoo Dentistry

Full name of responsible person

Hossein Baharian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Khosravani

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Email**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