Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

Phone
+98 31 3793 2100

Email address
z.khosravani@dnt.mui.ac.ir

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
Street address
Hazar Jarib Ave, Isfahan University of Medical Sciences, Faculty of Dentistry, Isfahan, Iran
City
Isfehan
Province
Isfehan
Postal code
7346181746
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

Street address

Hezarjarib Ave, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran.

City

Isfahan

Province

Isfehan

Postal code

7346181746

Phone

+98 31 3668 0048

Email

z.khosravani@dnt.mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Armita Vali Sichani

Street address

Hezarjarib, the Endodontics Department, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran.

City

Isfehan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

a.valisichani@dnt.mui.ac.ir

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
Street address
Hezarjarib, the Endodontics Department, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran.
City
Isfehan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
z.khosravani@dnt.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Armita Vali Sichani
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Hezarjarib Avenu, the Endodontics Department, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran.
City
Isfehan
Province
Isfehan
Postal code
0098 3136680048
Phone
+98 81 7467 3461
Email
a.valisichani@dnt.mui.ac.ir

Person responsible for updating data

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
Street address
Hezarjarib Avenu, the Endodontics Department, School of Dentistry, Isfahan University of Medical Sciences, Isfahan, Iran.
City
Isfehan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
z.khosravani@dnt.mui.ac.ir

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