

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The Addition of Clonidine to the Articaine/Epinephrine for Inferior Alveolar Nerve Block Reduces Postoperative Pain of Patients with Irreversible Pulpitis: A Randomized Clinical Trial

Protocol summary

Study aim

Determining and comparing the mean pain score at different times in the first 72 hours after endodontic treatment using articaine-epinephrine combination with and without clonidine

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 per 100 patients, dice were used for randomization

Settings and conduct

The study site is Isfahan School of Dentistry. The contents of the carpules are prepared by a dental student and are labeled on the carpule containing clonidine number 1 and on the carpule containing placebo 2. The endodontist rolls the dice immediately before the injection and injects the carpules with number 1 if it is individual and the carpules with number 2 if it is even. The content of carpules was not determined until after the analysis

Participants/Inclusion and exclusion criteria

Patient with a mandibular molar tooth with asymptomatic irreversible pulpitis

Intervention groups

Intervention group received 0.2 ml of clonidine with carpol with a volume of 1.8 ml containing articaine 4% and epinephrine 1: 100,000 The control group received 0.2 ml of distilled water with carpol with a volume of 1.8 ml containing articaine 4% and epinephrine 1: 100,000

Main outcome variables

VAS pain score

General information

Reason for update

Acronym

IANB

IRCT registration information

IRCT registration number: **IRCT20201031049199N1**

Registration date: **2020-11-17, 1399/08/27**

Registration timing: **retrospective**

Last update: **2020-11-17, 1399/08/27**

Update count: **0**

Registration date

2020-11-17, 1399/08/27

Registrant information

Name

Sara Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 1568

Email address

sara_hsh76@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-12, 1396/07/20

Expected recruitment end date

2018-02-09, 1396/11/20

Actual recruitment start date

2017-11-01, 1396/08/10

Actual recruitment end date

2018-03-11, 1396/12/20

Trial completion date

2018-03-11, 1396/12/20

Scientific title

The Addition of Clonidine to the Articaine/Epinephrine for Inferior Alveolar Nerve Block Reduces Postoperative Pain of Patients with Irreversible Pulpitis: A Randomized

Public title

Addition of clonidine to articaine solution in pain relief after root canal treatment

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged 15-60 ASA grade I Have symptomatic irreversible pulpitis in a mandibular posterior tooth

Exclusion criteria:

necessity for multi-visit treatments consumption of analgesics or opioids in a week periodontal problems underlying diseases such as diabetes, hypertension or other cardiovascular diseases an allergy or contraindication to clonidine, articaine, or epinephrine active signs of oral infection or inflammation Pregnant or lactating mothers drug abusers, and patients taking a β -blocker

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The clonidine-containing and non-clonidine cartridges were labelled No. 1 and No. 2, respectively. The solutions were prepared daily under aseptic conditions .Immediately before the injection, the endodontist, who was unaware of the contents of the cartridges, threw a dice. A No. 1 cartridge was used when an odd number came out and a No. 2 cartridge was used with an even number. Therefore, both the patient and the investigator were not aware of the content of the injected solution.

Blinding (investigator's opinion)

Double blinded

Blinding description

the anesthetic solutions were prepared and encoded by a dental student who was not involved in the study. Endodontist used a dice to choose which vial to use. The content of each number was not explained until the data analysis was done.

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

Hezar Jerib St., Isfahan University of Medical Sciences, Building No. 4 - Vice Chancellor for Research and Technology

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2017-10-02, 1396/07/10

Ethics committee reference number

IR.MUI.REC.1396.3.272

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

Post operative pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

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

Pain score

Timepoint

12 h after- 24 h after-36 h after- 48 h after-72 h after procedure

Method of measurement

Heft- parker visual analog scale

Secondary outcomes**1****Description**

Heart rate

Timepoint

Immediately Before administration- 5 minutes after administration

Method of measurement

digital blood pressure monitor (M3, Omron, omron healthcare co MTD, japan)

Intervention groups

1

Description

Intervention group: The clonidine group (Articaine + Epinephrine + Clonidine, n = 50) received an IANB with 0.2 ml clonidine (Catapressan amp., 150 µg/ml; BoehringerIngelheim, Ingelheim am Rhein, Germany) in addition to 1.8 ml of 4% articaine (Daropaksh, Tehran, Iran) with 1:100,000 epinephrine.

Category

Prevention

2

Description

Control group: The control group (Articaine + Epinephrine, n = 50) received an IANB with 0.2 ml distilled water in addition to 1.8 ml 4% articaine with 1:100,000 epinephrine (Daropaksh, Tehran, Iran)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry faculty of Isfahan University of Medical Sciences

Full name of responsible person

Elham Shadmehr

Street address

Shohadaye sofe St

City

Isfahan

Province

Isfahan

Postal code

87986546

Phone

+98 31 3440 8524

Email

elham.shadmer@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezar jarib St

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Web page address

<https://research.mui.ac.ir/>

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

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Elham Shadmehr

Position

Assistant professor of endodontic, Isfahan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Hezar jarib St

City

Isfahan

Province

Isfahan

Postal code

87986546

Phone

+98 31 3440 8524

Email

elham.shadmer@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Elham Shadmehr

Position

Assistant professor of endodontic, Isfahan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Dentistry faculty of Isfahan University of Medical Sciences, Hezar jarib St

City

Isfahan

Province

Isfahan

Postal code

87986546

Phone

+98 31 3440 8524

Email

elham.shadmer@gmail.com

Phone

+98 31 3669 1568

Email

Sara_hsh76@yahoo.com

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

VAS pain score and hemodynamic factors are shareable

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in scientific institutes.

Under which criteria data/document could be used

Data can be used if it is not in conflict with interests.

From where data/document is obtainable

Sara Hashemi 09134205038 Sara_hsh76@yahoo.com No. 32, 3rd Alley, 3rd Alley, South Resalat St., Sheikh Kolini St., Isfahan, Iran Postal Code: 8168964333

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

Email official documents related to the data requirements for a scientific project. Will be answered in a week.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Sara Hashemi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

3rd Ave, South Resalat St, Sheikh koleini St

City

Isfahan

Province

Isfahan

Postal code

۸۱۶۸۹۶۴۳۳۳