

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of effect of adding Dexmedetomidine to Lidocaine in success of inferior alveolar nerve block in patients with asymptomatic irreversible pulpitis

Protocol summary

Study aim

Comparing the effect of adding Dexmedetomidine to Lidocaine with plain Lidocaine in success of Inferior Alveolar Nerve block in patients with asymptomatic irreversible pulpitis.

Design

groups: 1. Lidocaine+ dexmedetomidine 2.Lidocaine
Sample size= 50 Double blinded Randomization,
Randomized block. single center.

Settings and conduct

An endodontist operates injections to the patients referred to Endodontic department of dental branch of Tehran Islamic Azad University . Operator and patients are blinded. Randomized block.

Participants/Inclusion and exclusion criteria

patients having a tooth with asymptomatic irreversible pulpitis ASA class I,II. not pregnant/ in lactation. not smoking and not addicted. not using psychologic drugs. haven't used sedatives or analgesics in past 24h before treatment. not having allergies to anesthetic drugs.

Intervention groups

adding Dexmedetomidine to Lidocaine or plain Lidocaine in local anesthesia.

Main outcome variables

Boosting the success of the Inferior Alveolar Nerve Block.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150815023620N8**

Registration date: **2018-07-08, 1397/04/17**

Registration timing: **retrospective**

Last update: **2018-07-08, 1397/04/17**

Update count: **0**

Registration date

2018-07-08, 1397/04/17

Registrant information

Name

Mohammadreza Moshari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2595

Email address

rmoshari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-03-19, 1396/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of adding Dexmedetomidine to Lidocaine in success of inferior alveolar nerve block in patients with asymptomatic irreversible pulpitis

Public title

Dexmedetomidine in success of nerve block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a tooth with asymptomatic irreversible pulpitis
ASA Cl I,II Age (between 18-65 ys)

Exclusion criteria:

Pregnancy Lactation Smoking Addiction taking
psychologic drugs taking sedatives/analgesics in last 24h
before treatment Having allergies to anesthetics
systemic disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: Randomized block method
with equal-sized group. Unit of randomization: Individual.
Tools: Statistical software excel version 10. Allocation
concealment: Coding of samples and sealed envelopes
placement.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double blinded; The operator and patients
are blinded since the operator(endodontist) receives a
sealed envelope containing drugs with code break
system. Patients are examined while are aware of
identity of study and declaration of consent from being
involved in study without being informed of the content
of drug. The evaluator measures and records the result
of Visual Analog Scale test and Electric Pulp Test

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Tehran,
Dental Branch

Street address

9th Neyestan aly., Pasdaran st.

City

Tehran

Province

Tehran

Postal code

19486

Approval date

2017-06-18, 1396/03/28

Ethics committee reference number

IR.IAU.DENTAL.REC.1396,7

Health conditions studied

1

Description of health condition studied

asymptomatic irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Inferior Alveolar Nerve blockage

Timepoint

during endodontic treatment

Method of measurement

visual analogue scale

2

Description

feeling of tingling

Timepoint

10min after intervention

Method of measurement

Electric pulp tester

Secondary outcomes

empty

Intervention groups

1

Description

intervention group:Dexmedetomidine 0.5μ\kg (0.4ml) +
Lidocaine 1.55%(1.4ml) Dexmedetomidine is
manufactured by Hospira. Each patient in Intervention
group recieves an Inferior Alveolar Nerve Block injection
containing described composition.

Category

Treatment - Drugs

2

Description

Control group: Lidocaine 2% (1.4ml) + Normal saline(0.4ml)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontics Department of Dentistry Faculty of
Tehran Azad University

Full name of responsible person

Zahra Vahedi

Street address

9th Neyestan aly., Pasdaran st.

City

Tehran

Province

Tehran

Postal code

19486

Phone

+98 21 2256 4570

Email

farva93@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Azad University, Dentistry Faculty

Full name of responsible person

Zahra Vahedi

Street address

9th Neyestan aly., Pasdaran st., Tehran.

City

Tehran

Province

Tehran

Postal code

19486

Phone

+98 21 2256 4570

Email

farva93@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran Azad University, Dentistry Faculty

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Amirabbas Moshari

Position

Endodontist

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

9th Neyestan aly., Pasdaran st.

City

Tehran

Province

Tehran

Postal code

19486

Phone

+98 21 2281 8161

Fax

Email

amirabbas.moshari@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammadreza Moshari

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

department of anesthesiology, Taleghani hospital,
Daneshjou ave. , velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 2595

Fax

Email

rmoshari@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Amirabbas Moshari

Position

endodontist

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

9th Neyestan aly., Pasdaran st. , Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

19486

Phone

+98 21 2256 4570

Fax

Email

amirabbas.moshari@gmail.com

Web page address

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