

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the Effect of Adding Magnesium Sulfate to Lidocaine/Epinephrine on the Success Rate of Inferior Alveolar Nerve Block in Patients with Irreversible Pulpitis

Protocol summary

Summary

The aim of this study is evaluation of the effect of adding Magnesium Sulphate to lidocaine/epinephrine on success rate of Inferior Alveolar Nerve Block in patient with Symptomatic Irreversible Pulpitis. Among the patients who are referred to Endodontics Department of Tehran Islamic Azad University from January to March 2017, 54 patients who have Irreversible pulpitis in lower molars are randomly allocated into two groups. Inclusion criteria: Patients with symptomatic irreversible pulpitis referred to endodontics Islamic Azad University in Tehran; willingness to participate in the study. Exclusion criteria: any systemic diseases, pregnancy and lactation, narcotic usage. Randomization will be performed using sealed envelopes among the patients who will agree to participate in the study and voluntarily sign consent form. To randomize the patients, a number will be allocated to each patient. The numbers are written on a piece of paper and then one will be kept in a separate sealed opaque envelope. Each patient will be asked to choose one of the envelopes and accordingly will be assigned to one of the two groups. To make the study double-blind, operators will be kept unaware about the type of anesthetic solution. Patients receive either 0.6ml Magnesium Sulfate 50% with 1.2ml Lidocaine2%/epinephrine1:100,000 or 0.6ml Normal saline with 1.2ml lidocaine 2%/ epinephrine1:100,000 in one cartridge as the anesthetic solutions for IANB. When Lip numbness is reported by the patients and after 3 times negative answer to Electric pulp test, Endodontic access preparation will be initiate within 9 minutes. Pain is the main outcome of interest. Success of IAN block is defined as no or mild pain rated on the visual analogue scale during access cavity preparation and initial instrumentation. Patients will be asked to report any pain and in the case of pain incidence, treatment will be stopped and pain rate will be assessed using VAS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110723620N3**
Registration date: **2017-02-11, 1395/11/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-11, 1395/11/23

Registrant information

Name

Mohammadreza Moshari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-12-10, 1395/09/20

Expected recruitment end date

2017-02-08, 1395/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effect of Adding Magnesium Sulfate to Lidocaine/Epinephrine on the Success Rate of Inferior Alveolar Nerve Block in Patients with Irreversible Pulpitis

Public title

Effect of Magnesium Sulfate on the Success rate of Inferior Alveolar Nerve Block

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with symptomatic irreversible pulpitis referred to endodontics Islamic Azad University in Tehran; willingness to participate in the study.

Exclusion criteria: any systemic diseases, pregnancy and lactation, narcotic using; cigarette smoking, analgesic drug usage during 24 hours before treatment, allergy to anesthetic drugs

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Dentistry branch, Tehran Islamic Azad University

Street address

No4, 10th Neyestan, Pasdaran Ave

City

Tehran

Postal code

19585/175

Approval date

2016-12-20, 1395/09/30

Ethics committee reference number

IR.IAU.DENTAL.REC.1395,16

Health conditions studied

1

Description of health condition studied

Irreversible Pulpitis

ICD-10 code

k04.0

ICD-10 code description

Diseases of pulp and periapical tissues

Primary outcomes

1

Description

Pain

Timepoint

During Access Cavity creation, During Exposure, Initial instrumentation

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Unset of anesthesia

Timepoint

3-6-9 minute after Intervention

Method of measurement

Electric pulp tester

Intervention groups

1

Description

Intervention group: 1.2 ml lidocain2% in combination with epinephrine 1/100000 (produced by DarouPakhsh Company) in addition to 0.6 ml Magnesium Sulphate 50%(produced by Pasteur Institute) will be prescribed in single dosage.

Category

Treatment - Drugs

2

Description

Control group: 1.2 ml Lidocaine2% in combination with Epinephrine1/100000 (produced by DarouPakhsh Company) in addition to 0.6 ml Normal Salin will be prescribed in single dosage.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

endodontics department, Dentistry branch, Tehran
Islamic Azad University

Full name of responsible person

Dr Amirabbas Moshari

Street address

No4, 10th Neyestan, Pasdaran Ave

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of research of Dental branch, Tehran
Islamic Azad University

Full name of responsible person

DR. Arash Azizi

Street address

No4, 10th neyestan , pasdaran Ave

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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

Vice Chancellor of research of Dental branch, Tehran
Islamic Azad University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Endodontics, School of Dentistry,
Islamic Azad University

Full name of responsible person

Dr Amirabbas Moshari

Position

Assistance profesor

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Person responsible for scientific inquiries

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Name of organization / entity

Anesthesia department, Shahid beheshti University of
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Full name of responsible person

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Assisstant professor

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Person responsible for updating data

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Name of organization / entity

Islamic Azad University of Dentistry

Full name of responsible person

Sepideh darabi

Position

Dental Student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty