Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 wiil 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

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Mohammadreza Moshari
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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 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

Other areas of specialty/work

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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