

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Effect of Adding Magnesium sulfate to Lidocaine 2%/Epinephrine 1/100000 on Post-operative Pain in Patient with Irreversible Pulpitis

Protocol summary

Summary

The aim of this study is to evaluate the Effect of Adding Magnesium sulfate to Lidocaine/epinephrine for Inferior Alveolar Nerve Block(IANB) on Post-operative Pain after Endodontic Treatment in Patient with Irreversible pulpitis. Among the patient who refer to Endodontic Department of Islamic Azad University of Dentistry in Tehran from January to March 2017, 54 patient who have Irreversible pulpitis in lower molars are randomly selected. All patients who will agree to participate in the study and voluntarily sign consent form are randomly divide into 2 groups of 27 patients each. To randomize the patients, each patient is assigned a number. The number in each group are write on paper, and each one will be kept in a separate sealed opaque envelope. Each patient will be asked to choose one of the envelopes and assign to one of the groups. To be Double-blind in this study, operators don't know the type of anesthetic solution. Patient 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. Each patient will be asked whether they have any signs of soft-tissue anesthesia, if the patients report anesthesia, endodontic treatment commence. Two-visit Root Canal Treatment(RCT) is done in all cases. After first visit, each patient records his pain score on a visual Analogue Scale(VAS) to rate their pain at 6, 12, 24, 48 hours after RCT. The patients are instruct that they can use analgesics (Ibuprofen 400mg) if they feel pain; however, they are also require to record the number of analgesic tablets on their VAS form. Patient with Systemic diseases and addict will be Excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110923620N4**

Registration date: **2017-02-13, 1395/11/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-13, 1395/11/25

Registrant information

Name

Mohammadreza Moshari

Name of organization / entity

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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

Evaluation of the Effect of Adding Magnesium sulfate to Lidocaine 2%/Epinephrine 1/100000 on Post-operative Pain in Patient with Irreversible Pulpitis

Public title

Effect of Magnesium sulfate on Post-operative Pain in Root Canal Therapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with symptomatic irreversible pulpitis referred to endodontics Islamic Azad University in Tehran to sign a consent form. Exclusion criteria: any systemic diseases, pregnancy and lactation, use of drugs, cigarettes, drugs, housing up to 24 hours before treatment, sensitivity to anesthetic

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

Experimental

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Dentistry

Street address

No 4, 10th Neyestan Alley, Pasdaran Ave

City

Tehran

Postal code

19585/175

Approval date

2016-12-20, 1395/09/30

Ethics committee reference number

IR.IAU.DENTAL.REC.1395,17

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

6, 12, 24, 48 hours after Intervention

Method of measurement

Visual Analogue Scale(0 to 170)

Secondary outcomes

1

Description

Number of Analgesic Tablets

Timepoint

6-12-24-48 hour after treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group:1.2 ml Lidocaine 2%/Epinephrine 1/100000(DarouPakhsh Company)+0.6 ml Magnesium sulfate 50%(Pasteur Institute) (Single dosage)

Category

Treatment - Drugs

2

Description

Control group: 1.2 ml Lidocaine2%/Epinephrine1/100000(DarouPakhsh Company) +0.6 ml Normal saline (Single Dosage)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University of Dentistry, Endodontic Department

Full name of responsible person

Dr Amirabbas Moshari

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Islamic azad university of dentistry

Full name of responsible person

DR. Arash Azizi

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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 for research of Islamic azad university of dentistry

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**

Islamic Azad University of Dentistry, Endodontic Department

Full name of responsible person

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Position

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Web page address**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