Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 wiil 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
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

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 Analouge 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
Street address
No 4, 10th Neyestan Alley, Pasdaran Ave
City
Tehran

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
Street address
No 4, 10th Neyestan Alley, 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 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
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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