Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Anesthetic efficacy of Dexamethasone added to Lidocaine for inferior alveolar nerve block in patients with symptomatic irreversible pulpitis

Protocol summary

Study aim

The purpose of this study was to compare the success rate of IAN block injection carried out with two cartridges of 2% lidocaine with 1:100000 epinephrine each combined with 0.2ml dexamethasone versus two cartridges of 2% lidocaine with 1:100000 epinephrine each combined with 0.2 ml sterile distilled water for endodontic treatment of mandibular molars with symptomatic irreversible pulpitis.

Design

Randomised, double-blinded clinical trial with a parallel group design of 100 patients randomly divided into two groups of 50 subjects each, using random number generator software.

Settings and conduct

Department of Endodontics, Dental School, Isfahan Each random number will be kept in a separate sealed opaque envelope. This procedure is done by a third person who has no clue and has not involved in the rest of the study and only the random number is used on the data collection sheets to further blind the experiment.

Participants/Inclusion and exclusion criteria

One hundred adult patients participated in this clinical trial. All of the subjects were in good health as determined by a health history and oral questioning. Exclusion criteria were as follows: Under 18 years of age, allergy to local anesthetics or sulfites, pregnancy, lactating and the inability to give written informed consent or understand the use of pain scales. Also patients with a periapical lesion (except for a widened periodontal ligament) were not included in this study. Therefore, to qualify for the study, each patient had a vital mandibular molar tooth with a clinical diagnosis of symptomatic irreversible pulpitis.

Intervention groups

Intervention group: 2 cartridges of 1.8 mL of 2% lidocaine with epinephrine each combined with 0.2 ml dexamethasone being injected. Control group: 2 cartridges of 1.8 mL of 2% lidocaine with epinephrine each combined with 0.2 ml sterile distilled water being injected.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091004002541N7**
Registration date: **2018-05-17, 1397/02/27**
Registration timing: **retrospective**

Last update: **2018-05-17, 1397/02/27**
Update count: **0**

Registration date

2018-05-17, 1397/02/27

Registrant information

Name

Masoud Saatchi

Name of organization / entity

School of Dentistry, Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-08-01, 1395/05/11

Expected recruitment end date

2017-08-01, 1396/05/10

Actual recruitment start date
2016-08-01, 1395/05/11
Actual recruitment end date
2017-07-23, 1396/05/01
Trial completion date
empty

Scientific title
Anesthetic efficacy of Dexamethasone added to Lidocaine for inferior alveolar nerve block in patients with symptomatic irreversible pulpitis

Public title
Anesthetic efficacy of Dexamethasone added to Lidocaine for inferior alveolar nerve block in patients with symptomatic irreversible pulpitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Eighteen years of age and over Being in good health condition Having a mandibular molar tooth with symptomatic irreversible pulpitis Normal periapical radiographic appearance (except for a widened periodontal ligament) Not having severe periodontal problem No history of allergy to local anesthesia or sulfite
Exclusion criteria:
Pregnancy or lactation Taking any medications that might cause altered pain sensation Any swelling or sinus tract near the target tooth Active sites of pathosis in the area of injection Inability of the patient to give an informed consent Lack of lip numbness within 15 minutes after injection
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients choose the envelope with simple random sampling protocol to determine which anesthetic solution will be administered.
Blinding (investigator's opinion)
Double blinded
Blinding description
Five-digit random numbers are being generated by using computer random numbers and they are written on a label on the anesthetic solutions. Each random number will be kept in a separate sealed opaque envelope. All these procedures is done by a third person who has no clue and has not involved in the rest of the study and only the random number is used on the data collection sheets to further blind the experiment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran.
City
Isfahan
Province
Isfehan
Postal code
81744-73461
Approval date
2016-07-01, 1395/04/11
Ethics committee reference number
396731

Health conditions studied

1

Description of health condition studied
Irreversible pulpitis
ICD-10 code
K04.0
ICD-10 code description
Pulpitis

Primary outcomes

1

Description
Pain
Timepoint
Before treatment and after initiating root canal therapy
Method of measurement
Heft-Parker visual analog scale (VAS)

Secondary outcomes

1

Description
Post pain
Timepoint
During procedure
Method of measurement
Heft-Parker visual analog scale (VAS)

Intervention groups

1

Description
Intervention group: 2 cartridges of 1.8 mL of 2% lidocaine with epinephrine each combined with 0.2 ml dexamethasone applied by using conventional inferior alveolar nerve block injection technique.
Category
Treatment - Drugs

2

Description
Control group: 2 cartridges of 1.8 mL of 2% lidocaine with epinephrine each combined with 0.2 ml sterile distilled water applied by using conventional inferior alveolar nerve block injection technique.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Endodontics, Dental School, Isfahan
Full name of responsible person
Masoud Saatchi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences
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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, Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Masoud Saatchi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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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