Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Sodium Bicarbonate Buffered Lidocaine 2% on the Success of Inferior Alveolar Nerve Block for Teeth with Symptomatic Irreversible Pulpitis

Protocol summary

Summary

The purpose of this clinical trial study is to compare the anesthetic efficacy of a buffered with a non-buffered 2% lidocaine with 1:80,000 epinephrine solution for inferior alveolar nerve block in patients with mandibular posterior teeth experiencing symptomatic irreversible pulpitis. Eighty adult patients diagnosed with symptomatic irreversible pulpitis of a mandibular posterior tooth will be selected.All were emergency patients of dental clinic of Isfahan University of Medical Sciences.The patientswill be received two cartridges of either 1.5 mL of 2% lidocaine with 1:80,000 epinephrine buffered with 0.3 mL of 8.4% sodium bicarbonate or 1.5 mL of 2% lidocaine with 1:80,000 epinephrine with 0.3 mL of sterile distilled water using conventional IAN block injections. Endodontic access preparation will be begun 15 minutes after injection. Lip numbness is required for all patients. If the patient felt pain during access cavity preparation or initial file placement, the treatment was immediately ceased and the patient rated the discomfort by using Heft-Parker visual analog scale. Success will be determined as no or mild pain on the basis of Heft-Parker visual analog scale recordings upon endodontic access or initial instrumentation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090219021N1**
Registration date: **2014-09-13, 1393/06/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-13, 1393/06/22

Registrant information

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Recruitment status

Recruitment complete

Funding source

Iisfahan University of Medical Science

Expected recruitment start date

2014-09-13, 1393/06/22

Expected recruitment end date

2014-12-13, 1393/09/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Sodium Bicarbonate Buffered Lidocaine 2% on the Success of Inferior Alveolar Nerve Block for Teeth with Symptomatic Irreversible Pulpitis

Public title

Effect of Sodium Bicarbonate Buffered Lidocaine 2% in the treatment of teeth with acute pain

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age 20-60 years; no history of systemic

diseases; lower molars with symptomatic irreversible pulpitis exclusion criteria: active sites of pathosis in the area of injection; Lack of lip numbness within 15 minutes after injection

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan Regional Bioethics Committee

Street address
University of Medical Sciences

City
Isfahan

Postal code
8174673461

Approval date
2014-08-09, 1393/05/18

Ethics committee reference number
193396

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
degree of initial pain

Timepoint
before root canal therapy

Method of measurement
visual analogous scale

Secondary outcomes

1

Description
degree of Secondary pain

Timepoint
during root canal therapy

Method of measurement
visual analogous scale

Intervention groups

1

Description
patients will divided into two groups. 2 inferior alveolar nerve block with 2 similar cartridges will be injectet to each patient. . Endodontic access preparation will be begun 15 minutes after injection. Lip numbness is required for all patients.the patients in the control group will be received two cartridges of 1.5 mL of 2% lidocaine (Lignospan; Septodont, Saint Maur des Fosses, France) with 1:80,000 epinephrine with 0.3 mL sterile distilled water

Category
Treatment - Drugs

2

Description
patients will divided into two groups. 2 inferior alveolar nerve block with 2 similar cartridges will be injectet to each patient. . Endodontic access preparation will be begun 15 minutes after injection. Lip numbness is required for all patients.the patients in the first experimental group will be received two cartridges of 1.5 mL of 2% lidocaine with 1:80,000 epinephrine(Lignospan; Septodont, Saint Maur des Fosses, France) buffered with 0.3 mL of 8.4% sodium bicarbonate (8.4% weight/volume, 50 mEq/50 mL, Samen Laboratories, Iran).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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Department of Research and Technology, Building No. 4, Central Organ of University, 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
Isfahan University of Medical Sciences
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

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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