Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of supplementary infiltration injection of Sodium Bicarbonate on success rate of IANB of mandibular first molars with irreversible pulpitis: A Randomized, Clinical, Double-blind Study

Protocol summary

Summary

The aim of this single-center phase 2 prospective , randomized, double-blind clinical trial, is to investigate effect of sodium bicarbonate injection infiltration on inferior alveolar nerve block success rate in teeth with irreversible pulpitis compared to infiltration injection of sterile water as placebo in the same teeth. 100 healthy patients over 18 years old that do not take any medication with diagnosis of symptomatic irreversible pulpitis in mandibular first molar teeth by use of cold test were selected.Patients and physician were blind about liquid in infiltration injection were drug or placebo therefore the study considered as a double-blind study. In the first group (Group buffer) before the mandibular alveolar nerve block injection, 0.7 ml of sodium bicarbonate with 0.3 ml of 8.4% lidocaine (to reduce pain during injection) measured by use of a Hamilton syringe injected as an supplementary infiltration injection to distal of first molar. The same amount of distilled water and Lidocaine used in placebo group. After 15 minute if lip numbness not happened in patient 3.8 ml of lidocaine injected as inferior alveolar nerve block. Success defines as no or mild pain according to Heft-Parker visual analog scale (VAS).

General information

Acronym

IANB=inferior alveolar nerve block

IRCT registration information

IRCT registration number: **IRCT201409142541N4**
Registration date: **2016-05-24, 1395/03/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-24, 1395/03/04

Registrant information

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Masoud Saatchi
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supplementary infiltration injection of Sodium Bicarbonate on success rate of IANB of mandibular first molars with irreversible pulpitis: A Randomized, Clinical, Double-blind Study

Public title

Effect of sodium bicarbonate on success of inferior alveolar anesthesia

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:18 years of age and over; being in good health condition;having a mandibular first molar tooth with symptomatic irreversible pulpitis;not having periodontal problem; normal periapical radiographic appearance (other than a widened periodontal ligament); and normal periapical radiographic appearance (other than a widened periodontal ligament); no history of allergy Exclusion criteria: History of any systemic disorders, lactation, pregnancy, allergy to Local anesthesia, taking any medications that might influence anesthetic assessment, presence of periradicular radiolucency, swelling or having fistula near target tooth, active sites of pathosis in area of injections, or any problem that patient could not give informed consent; lack of lip numbness within 15 minutes after mandibular alveolar nerve block injection
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Single
Other design features
Patients and physician were unaware that liquid in infiltration injection were drug or placebo therefore the study considered as a double-blind study.

Secondary Ids

1

Registry name
ClinicalTrials.gov ID: NCT02726737
Secondary trial Id
941234
Registration date
2016-04-01, 1395/01/13

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. P.O.Box: 81744-176.
City
Isfahan
Postal code
8174673461
Approval date
2016-02-04, 1394/11/15
Ethics committee reference number
IR.MUI.REC.1394.3.1020

Health conditions studied

1

Description of health condition studied
irriversible pulpitis
ICD-10 code
K04.0
ICD-10 code description
Pulpitis: NOS acute chronic (hyperplastic)(ulcerative) irreversible reversible

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 recording of pain

Intervention groups

1

Description
infiltration injection involved 0.7 ml of distilled water and 0.3 ml of 2% lidocaine with 1.80000 epinephrine
Category
Placebo

2

Description

infiltration injection involved 0.7 ml of sodium bicarobonate and 0.3 ml of 2% lidocaine with 1.80000 epinephrine

Category
Treatment - Drugs

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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Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran. P.O.Box: 81744-176

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Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person
Masoud Saatchi

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City
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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
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
Isfahan University of Medical Sciences

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Position
professor

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