

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Masoud Saatchi

Name of organization / entity

School of Dentistry, Isfahan University of Medical Sciences

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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

irreversible 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 bicarbonate 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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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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Vice chancellor for research, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran. P.O.Box: 81744-176

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Isfahan

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

Full name of responsible person

Masoud Saatchi

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