Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Supplementary Anesthesia of Mental Incisive Nerve Block, and Buccal Infiltration on Anesthetic Success of Inferior Alveolar Nerve Block, using 4% Articaine in Mandibular First Molars with Symptomatic Irreversible Pulpitis: A Double Blind Randomized Clinical Trial

Protocol summary

Study aim

Determination of the effect of Supplementary Incisive nerve block and buccal infiltration on the success of inferior alveolar nerve block, using 4% articaine on anesthesia of mandibular first molars with symptomatic irreversible pulpitis

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 75 patients. A random number table was used for randomization.

Settings and conduct

A total of 75 patients with inclusion criteria who referred to Alborz Dental Clinic in Urmia.

Participants/Inclusion and exclusion criteria

Criteria for inclusion in this study include healthy adults aged 18 to 60 years, first molars with irreversible pulpitis on one side of the mandible, and normal periapical radiographs. Exclusions of this study include systemic disease, patients with severe stress, patients with toothache at the time of study, unstable heart disease, sensitivity to 4% articaine anesthetic with epinephrine or latex, facial or oral paraesthesia, use of any analgesic In the 12 hours before treatment, the use of psychotropic and neurological drugs, asymptomatic irreversible pulpitis, the presence of periapical radiolucency, pregnancy, lactation, irreparable teeth and the presence of veneers on the teeth.

Intervention groups

1. The group receiving the incisor nerve block supplemental anesthesia 2. The group receiving the infiltration supplemental anesthesia 3. The group that does not receive any supplemental anesthesia

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180513039638N2**
Registration date: **2021-05-11, 1400/02/21**
Registration timing: **prospective**

Last update: **2021-05-11, 1400/02/21**
Update count: **0**

Registration date

2021-05-11, 1400/02/21

Registrant information

Name

Amir Ardalan Abdollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3336 3600

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-14, 1400/02/24

Expected recruitment end date

2021-10-16, 1400/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Supplementary Anesthesia of Mental Incisive Nerve Block, and Buccal Infiltration on Anesthetic Success of Inferior Alveolar Nerve Block, using 4% Articaine in Mandibular First Molars with Symptomatic Irreversible Pulpitis: A Double Blind Randomized Clinical Trial

Public title
The effect of Supplementary Anesthesia of Mental Incisive Nerve Block and Buccal Infiltration on the Success of Inferior Alveolar Nerve Block

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with symptomatic irreversible pulpitis in the mandibular permanent first molars Healthy adults aged 18 to 60 years Normal periapical radiograph

Exclusion criteria:
Existence of systemic disease Patients with severe stress Patients with toothache at the time of study Unstable heart disease Allergy to 4% articaine anesthetic with epinephrine or latex Facial or oral paraesthesia Use any painkiller 12 hours before treatment Taking psychotropic drugs Asymptomatic irreversible pulpitis cases Presence of periapical radiolucency Pregnancy and lactation Irreparable teeth and the presence of crowns on the teeth

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done in a simple, individual way with the help of Random.org and by the assistant. Patients were divided into three treatment groups using random numbers generated by Random.org.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be double-blind in the sense that both patients and the person evaluating the results will not be aware of the study conditions. The person in charge of analyzing and interpreting the data also does not know how to choose.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Alborz St., Alborz Dental Clinic

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2020-11-29, 1399/09/09

Ethics committee reference number
IR.UMSU.REC.1399.268

Health conditions studied

1

Description of health condition studied
irreversible puplitis

ICD-10 code
B95

ICD-10 code description
Streptococcus and staphylococcus as the cause of diseases classified to other chapters

Primary outcomes

1

Description
anesthesia

Timepoint
Once every 4 minutes, up to 15 minutes after anesthesia injection

Method of measurement
Electric Pulp Tester

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After inferior alveolar nerve block,

supplementary anesthesia of mental nerve block is performed for this group .

Category

Treatment - Drugs

2

Description

Intervention group: After inferior alveolar nerve black, additional infiltration anesthesia is performed for this group.

Category

Treatment - Drugs

3

Description

Control group: Only Inferior alveolar nerve block anesthesia is performed for this group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alborz Dental Clinic of Urmia

Full name of responsible person
Amir Ardalan Abdollahi

Street address
Alborz Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Iraj Mohebbi

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Alborz Street

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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
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Amir Ardalan Abdollahi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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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