Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of effect of submucosal injection of Dexamethasone in comparison with buccal infiltration of Articaine for inferior alveolar nerve block success improvement in mandibular first molars with symptomatic irreversible pulpitis: a randomized double-blind clinical trial

Protocol summary

Study aim
Comparison of effect of dexamethasone and articaine in improving the efficiency of IANB

Design
Randomized clinical trial including Case and Control, Double blinded, Phase is not applicable, Parallel group design of 96 patients, Simple Randomization has been used

Settings and conduct
This double-blind randomized clinical trial will be conducted on 96 patients diagnosed with symptomatic irreversible pulpitis in mandibular first molars. patients will be randomly allocated into two equal groups after receiving inferior alveolar nerve block anesthesia using lidocaine. in the intervention group, a submucosal injection of dexamethasone will be administered, while in the control group, buccal infiltration of Articaine will be performed. Pain intensity will be assessed using the cold spray test, VAS and ESM. Two operators are involved, one for injection of anesthesia and solutions, the other for treatment and examination.

Participants/Inclusion and exclusion criteria
Inclusion: Lower first Molar with irreversible pulpitits Systemically healthy patient Pretreatment moderate to severe pain Ages 18-55 y.o Able to cooperate Positive response to cold and electrical test Written informed consent letter Exclusion: Uncontrolled systemic disease Allergies to Lidocaine, Dexamethasone, Articaine or Epinephrine Pregnant or nursing women Anti-inflammatory drugs use in recent 2 weeks Painkiller use in recent 12 hours Acute infection, Abscess or Fistula History of unsuccessful Endodontic treatment Narcotics or alcohol use contraindications to Dexamethasone Crown or root fracture Calcification of pulp or canals

Intervention groups
Control: IANB by Lidocaine + Buccal infiltration of Articaine Case: IANB by Lidocaine + Submucosal injection of Dexamethasone

Main outcome variables
Inferior Alveolar nerve block success

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260617069848N1**
Registration date: **2026-07-29, 1405/05/07**
Registration timing: **prospective**

Last update: **2026-07-29, 1405/05/07**
Update count: **0**

Registration date
2026-07-29, 1405/05/07

Registrant information

Name
Seyed Mohammad Mousavi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-02, 1405/05/11

Expected recruitment end date

2026-12-12, 1405/09/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of submucosal injection of Dexamethasone in comparison with buccal infiltration of Articaine for inferior alveolar nerve block success improvement in mandibular first molars with symptomatic irreversible pulpitis: a randomized double-blind clinical trial

Public title

Comparison of two adjunctive methods for improving anesthetic success in Root Canal Treatment of teeth with severe pulpal inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy patients classified as ASA I , ASA II: People without severe systemic diseases that can affect the outcome of anesthesia or treatment Ages between 18-55 y,o: This range was selected in order to reduce the effects of age on neural system's response to anesthesia and inflammation Lower Molars diagnosed with irreversible pulpitis: Based on clinical examinations, it is considered as teeth with spontaneous pain, pain in response to thermal stimulant and sensitivity to cold and electrical test Moderate to severe pain (VAS≥4): Confirming that the patient needs effective anesthesia Teeth without Abscess, Fistula or widespread infection: Presence of severe infection can have negative impacts on anesthesia's effectiveness and response to treatment Positive response to cold and electrical test: Confirmation of relatively healthy pulpal nerve and presence of active pulpitis Capable of cooperation and fully acknowledging the process of treatment and examinations: Patients should be able and willing to follow the instructions and examinations Informed written consent letter: According to principles of Medical Research Ethics

Exclusion criteria:

Allergic reactions to Dexamethasone, Lidocaine, Articaine or Epinephrine: including previous or known reactions Uncontrolled systemic diseases: Including poorly controlled type 1 and 2 diabetes, cardiovascular, Liver, Renal diseases or Immunodeficiencies that can affect the process of treatment Pregnant or nursing women: Considering the limitation of using drugs in these two groups Consumption of Corticosteroids or potent Anti-Inflammations in recent two weeks: In order to prevent the systemic effects of drug interference on the results Presence of Acute infection, Abscess or active Fistula at the site of treatment: Can reduce the effectiveness of anesthesia Teeth with root or crown fracture that require complicated treatments: Confirming the integrity of structure and reducing the confounding factors in analysis of anesthesia History of unsuccessful Endodontic treatment of the intended tooth: Other factors might be involved in failure Patients that are not capable to cooperate or follow the instructions: Including patients with mental disorders or severe physical disability Consumption of Narcotics or Alcohol: Can affect the sensitivity to pain and response to anesthesia Patients under medications or particular psychological treatments that can affect the sensitivity to pain and response to anesthesia: For example Antidepressant or Anxiolytic drugs Patients with previous trauma to Molars Calcification of pulp and root canals Patients with Contraindications (Relative or Absolute) to Dexamethasone Patients that have consumed painkillers in the recent 12 hours

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

To Randomize the samples and Allocation of patients into two groups, a list containing 96 sequential numbers (Sample size) from 1 to 96 will be provided. Of these 96 numbers, 48 will be assigned to the control group and 48 to the intervention group, and the order of these allocations in the list will be determined completely at random, without following any specific or predictable pattern. For example, the first number may be assigned to the control group, and the subsequent number to the intervention group. This process will continue until all 96 allocations have been assigned. The final group-allocation list will be accessible only to the student responsible for conducting the study. When each eligible patient presents for treatment, the operator will communicate only the patient's enrollment number to the student. The solution corresponding to the assigned group (articaine for the control group or dexamethasone for the intervention group) will then prepared according the allocation corresponding to that number in the pre-prepared list and provided to the operator. Thus, patients will be allocated to the study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

To ensure blinding, two operators are involved in the study. One operator is responsible for administering the anesthesia and the assigned supplementary intervention (Dexamethasone for intervention group and Articaine for control group), while the second operator performs the root canal treatment and assessed pain intensity throughout the procedure.

Placebo

Not used

Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
University of medical science of Tabriz, Golgasht St., Azadi Blvd.
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2026-06-08, 1405/03/18
Ethics committee reference number
IR.TBZMED.REC.1405.157

Health conditions studied

1

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

Primary outcomes

1

Description
Percentage of patients with successful anesthesia during the root canal treatment
Timepoint
During the preparation of access cavity and initial instrumentation of root canal
Method of measurement
Pain intensity reported by patient and lack of need for repetition of the administration of anesthesia

Secondary outcomes

1

Description
Pain intensity during treatment based on VAS
Timepoint
During the preparation of access cavity and initial instrumentation of root canal
Method of measurement
Visual Analogue Scale in range of 0 to 10

2

Description
Pain intensity during treatment based on ESM
Timepoint
During the preparation of access cavity and initial instrumentation of root canal
Method of measurement
Observing signs of ESM including opening or closing eyes, making sounds, body motions. 1 score for each one

3

Description
Need for repetition of anesthesia
Timepoint
During root canal treatment
Method of measurement
The requirement for re-administration of anesthesia by the operator. recorded as a Yes/No

Intervention groups

1

Description
Intervention group: Receiving 1.8 ml of Lidocaine 2% with Epinephrine 1:80000 (Lignocaine 2% with Epinephrine Sahand Daroo pharmaceutical company) and 1ml of Dexamethasone (Dexadic 8mg/2ml Caspian pharmaceutical company), equal to 36mg of Lidocaine and 4 mg of Dexamethasone
Category
Treatment - Drugs

2

Description
Control group: Receiving 1.8 ml of Lidocaine 2% with 1:80000 Epinephrine (Lignocaine 2% with Epinephrine Sahand Daroo pharmaceutical company) and 1.8 ml of Articaine 4% with Epinephrine 1:200000 (Dentacain 200 with Epinephrine Exir pharmaceutical company), equal to 36mg of Lidocaine and 72mg of Articaine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Special clinic of faculty of Dentistry of Tabriz
Full name of responsible person
Shaghayegh Ghadimi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Khosro Adibkia
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Shaghayegh Ghadimi
Position
Assistant 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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Deindentified individual participant data collected during the study

When the data will become available and for how long

After study completion and publication of the main results

To whom data/document is available

Qualified researchers upon reasonable request and approval

Under which criteria data/document could be used

For scientific research purposes only and subject to participant confidentiality requirements

From where data/document is obtainable

Principal investigator of the study

What processes are involved for a request to access data/document

Requests will be reviewed and data may be shared upon approval by the research team and in accordance with ethical requirements

Comments