Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the Effects of Oral Steroidal and Non-Steroidal Anti-Inflammatory Drugs on Pain Severity Following Inferior Alveolar Nerve Block in Mandibular Molars with Symptomatic Irreversible Pulpiti(A Double-Blind Randomized Clinical Trial)

Protocol summary

Study aim
Primary Objective: Compare pre-treatment oral steroids and NSAIDs on success of inferior alveolar nerve block anesthesia in symptomatic irreversible pulpitis of mandibular molars. Secondary Objectives: Determine anesthesia success in control and each drug group (prednisolone, dexamethasone, naproxen, piroxicam, diclofenac). Compare success among groups.

Design
A randomized, double-blind, parallel-group, community-based, pragmatic clinical trial with a control group.

Settings and conduct
This study will be conducted at the endodontics specialist's clinic and includes patients referred for endodontic treatment. Sampling will be convenience-based according to inclusion criteria until the required sample size is reached. Eligible participants will be stratified based on gender, age, and pain severity, and then randomly assigned into six groups using the blockrand package in R software. Patients' pain levels will be recorded at four different stages of the procedure using the Heft-Parker VAS scale, and anesthesia success will be defined based on pain intensity.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Systemically healthy (ASA I) patients aged 18-60 with symptomatic irreversible pulpitis in mandibular molars, no periapical changes (Periapical Index ≤ 2), able to use pain scale. Exclusion Criteria: Teeth with trauma, open apex, pulp necrosis; systemic disease; immunodeficiency; pregnancy; allergies; recent (within 12h) antibiotic, analgesic or sedative use; long-term medication; unable to consent.

Intervention groups
Six groups received oral premedication: naproxen 500 mg, dexamethasone 4 mg, prednisolone 20 mg, piroxicam 20 mg, diclofenac 50 mg, and placebo (dextrose).

Main outcome variables
Pain during procedure; success of anesthesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250815066862N1**
Registration date: **2025-08-26, 1404/06/04**
Registration timing: **prospective**

Last update: **2025-08-26, 1404/06/04**
Update count: **0**

Registration date
2025-08-26, 1404/06/04

Registrant information

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Mahsa Mehrban

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-06, 1404/06/15

Expected recruitment end date
2025-10-07, 1404/07/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the Effects of Oral Steroidal and Non-Steroidal Anti-Inflammatory Drugs on Pain Severity Following Inferior Alveolar Nerve Block in Mandibular Molars with Symptomatic Irreversible Pulpiti(A Double-Blind Randomized Clinical Trial)

Public title
Effects of Oral Steroidal and Non-Steroidal Anti-Inflammatory Drugs on Pain Severity following Inferior Alveolar Nerve Block in
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Systemically healthy patients (ASA 1) aged 18 to 60 years with molars with symptomatic irreversible pulpitis (with a history of moderate to severe pain and pain lasting more than 45 seconds on pulp sensibility test) No periapical changes on radiographs (periapical index ≥ 2) Participants who understood the method of using the pain scale.
Exclusion criteria:
Systemic disease, immunodeficiency, pregnancy, history of allergy to local anesthetic solutions or any experimental drug The patient is unable to provide informed consent. Taking antibiotics, painkillers, and sedatives up to twelve hours before root canal treatment as part of a study and long-term use of medications. Teeth with trauma, open apex, pulp necrosis (no bleeding observed after access cavity preparation).
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **210**
Randomization (investigator's opinion)
Randomized
Randomization description
Sequence Generation and Allocation Concealment: To minimize bias in the allocation of participants to study groups, the random sequence will be generated by an independent individual who is not involved in the conduct of the trial. Participants will be assigned to six treatment groups using the SPSS software and a computer-generated random number generator. The generated sequence will be kept confidential with restricted access to ensure allocation concealment. Therefore, the research team will remain unaware of the group assignment of each participant in advance.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will use a double-blind design, meaning that both participants and outcome assessors will be unaware of the treatment group assignments. The interventions are designed to be similar in appearance and administration to prevent identification of the groups. The purpose of blinding is to minimize bias during data collection and analysis. The medications/interventions used in the groups will have identical appearance, packaging, and administration to ensure that neither participants nor assessors can identify the assigned groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Khorramabad University of Medical Sciences
Street address
Shafiepoor blvd
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6814989468
Approval date
2025-08-13, 1404/05/22
Ethics committee reference number
IR.LUMS.REC.1404.194

Health conditions studied

1

Description of health condition studied
Oral Steroidal and Non-Steroidal Anti-Inflammatory , Symptomatic Irreversible Pulpiti
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
1. Success of Inferior Alveolar Nerve Block Anesthesia:The proportion of patients experiencing no pain or mild pain (0–54 mm) measured by the Heft-Parker Visual Analog Scale (VAS) during root canal treatment.2. Pain Intensity During Procedure:The level of pain reported by patients at different stages of treatment (before medication, after local anesthesia, during access cavity preparation, and during file placement) measured by the Heft-Parker VAS.

Timepoint
Pain intensity will be measured using the Heft-Parker VAS at four specific time points during the root canal treatment:1. Before premedication administration (baseline)2. After administration of local anesthesia3. During access cavity preparation4. During file placement in the root canals

Method of measurement
Method of measuring the primary outcome variable:Pain intensity is measured using the Heft-Parker Visual Analog Scale (VAS), which consists of a 170-mm line divided into four categories: no pain (0 mm), mild pain (0–54 mm), moderate pain (55–114 mm), and severe pain (115–170 mm). Patients are trained to mark their pain level on this scale. Pain scores are recorded at each treatment stage and used to determine the success or failure of the anesthesia.

Secondary outcomes

empty

Intervention groups

1

Description
Control group (Placebo):Oral premedication with one capsule containing dextrose as placebo, administered one hour before anesthesia, single oral dose. Capsules are identical in shape, size, and color to the intervention drugs, prepared in sealed, sequentially numbered envelopes.Intervention group 1 (Naproxen):Oral premedication with one 500 mg naproxen tablet (manufactured by [Company/Country]), administered one hour before anesthesia, single oral dose.Intervention group 2 (Dexamethasone):Oral premedication with one 4 mg dexamethasone tablet (manufactured by [Company/Country]), administered one hour before anesthesia, single oral dose.Intervention group 3 (Prednisolone):Oral premedication with one 20 mg prednisolone tablet (manufactured by [Company/Country]), administered one hour before anesthesia, single oral dose.Intervention group 4 (Piroxicam):Oral premedication with one 20 mg piroxicam capsule (manufactured by [Company/Country]), administered one hour before anesthesia, single oral dose.Intervention group 5 (Diclofenac):Oral premedication with one 50 mg diclofenac potassium tablet (manufactured by [Company/Country]), administered one hour before anesthesia, single oral dose.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Private Endodontic Clinic, Dr. Maryam Dalaei Moghaddam

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Khoram-Abad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Dr. Maryam Dalaei Moghaddam

Position
Faculty Member, Faculty of Dentistry, Lorestan University of Medical Sciences, Khorramabad

Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
De-identified individual participant data (including age, gender, treatment allocation, and pain scores on Heft-Parker VAS), study protocol, case report forms (CRFs), and statistical analysis plan.

When the data will become available and for how long
Data will be available within 6 months after completion of the study and publication of the primary results.Data will be available for at least 3 years after publication of the study results.

To whom data/document is available
Access to the data will be granted only to qualified researchers upon written request and approval by the

ethics committee.

Under which criteria data/document could be used

The data will be available exclusively for research and scientific purposes in the field of dentistry, endodontics, and pain management. Use of the data requires maintaining patient confidentiality, de-identification of all information, and prior approval by the ethics committee. Data sharing for non-scientific or commercial purposes will not be permitted.

From where data/document is obtainable

Requests should be directed to the principal investigator, Dr. Maryam Dalaei Moghaddam (Faculty Member, Faculty of Dentistry, Lorestan University of Medical Sciences, Khorramabad, Iran).

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

Upon receiving a written request from a researcher, the application will be reviewed by the university ethics committee. If approved, de-identified data will be provided to the applicant in Excel or SPSS format. Access will be granted only for legitimate scientific and research purposes.

Comments