

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of premedication with oral Dexamethasone on the success of inferior alveolar nerve block for teeth with irreversible pulpitis: A double blind randomized clinical trial

Protocol summary

Summary

Objectives; pain control during dental procedure is one of the most important goals of dentists. The most conventional method for anesthetizing mandibular molar teeth is inferior alveolar nerve block (IANB). The aim of the present study is to assess the effect of dexamethasone (0.5 mg) administered as a single, preoperative oral dose on the success rate of IANB. Design; in a randomized double-blinded clinical trial, 100 patients (50 per group) with irreversible pulpitis will participate in this study. Setting and conduct; the patients who would be selected for the study will be given the placebo or 0.5 mg oral dexamethasone 1 hour before the local anesthesia. Endodontic treatments will start for the patients who reported lip numbness 15 minutes after the injection. If the patients felt an intolerable pain during the procedure, a supplementary injection will be administered. In those situations the IANB will be considered as an unsuccessful injection. The numbers of successful IANBs in two groups (placebo and dexamethasone) will be compared using Chi-square and Fisher's exact tests. Participants including major eligibility criteria: Major inclusion criteria; patients with the diagnosis of symptomatic irreversible pulpitis of a posterior mandibular tooth; patients who read and sign the informed consent. Major exclusion criteria; presence of systemic disorder; sensitivity to lidocaine or SAIDs; pregnancy; lactation; history of gastrointestinal ulcer; history of using pain medications 12 hours before the endodontic procedure. Intervention; asking patients of first and second groups to take 0.5 mg oral dexamethasone and placebo respectively 1 hour before the local anesthesia. Main outcome measures variables; intolerable pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112515540N1**
Registration date: **2013-12-26, 1392/10/05**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-12-26, 1392/10/05

Registrant information

Name

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Name of organization / entity

Qazvin university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin school of dentistry, Qazvin university of medical sciences.

Expected recruitment start date

2014-01-01, 1392/10/11

Expected recruitment end date

2014-03-01, 1392/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of premedication with oral Dexamethasone on the success of inferior alveolar nerve block for teeth with irreversible pulpitis: A double blind randomized clinical trial

Public title

Effect of Dexamethasone on the success of local anesthesia during root canal treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Major inclusion criteria; patient with the diagnosis of symptomatic irreversible pulpitis of a posterior mandibular tooth; patients who read and sign the informed consent. Major exclusion criteria; presence of systemic disorder; sensitivity to lidocaine or SAIDs; pregnancy; lactation; history of gastrointestinal ulcer; history of using pain medications 12 hours before the endodontic procedure.

Age

From **18 years** old

Gender

Both

Phase

2-3

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

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

Street address

Ethics Committee of Qazvin University of Medical Sciences, faculty of nursing, Qazvin university of medical sciences, Bahonar Blvd.

City

Qazvin

Postal code

3415759811

Approval date

2013-03-18, 1391/12/28

Ethics committee reference number

28/20/8101

Health conditions studied**1****Description of health condition studied**

Irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Diseases of pulp and periapical tissues

Primary outcomes**1****Description**

Pain during root canal treatment

Timepoint

during treatment

Method of measurement

visual analogue scale (VAS), which consists of a 10-cm line anchored by 2 extremes, "no pain" and "pain as bad as it could be"

Secondary outcomes

empty

Intervention groups**1****Description**

Premedication with single dose oral dexamethasone (0.5 mg), one hour before endodontic procedure.

Category

Treatment - Drugs

2**Description**

Premedication with single dose placebo (dextrose gelatin capsule), one hour before endodontic procedure.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endodontic department, Qazvin school of dentistry, Qazvin university of medical sciences

Full name of responsible person

Ali Fardnia

Street addressEndodontic department, Qazvin school of dentistry,
Qazvin university of medical sciences, Bahonar Blvd.**City**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Qazvin university of medical science

Full name of responsible person

Nima Moradi Majd

Position

Assistant professor

Other areas of specialty/work**Street address**Endodontic department, Qazvin school of dentistry,
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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research, Qazvin School of
Dentistry**Full name of responsible person**

Katayoun Borhanmojabi

Street addressQazvin school of dentistry, Qazvin University of
Medical Sciences, Bahonar Blvd.**City**

Qazvin

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, Qazvin School of Dentistry

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**

Qazvin university of medical sciences

Full name of responsible person

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Assistant professor

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Web page address**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