

# 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

Nima Moradi Majd

##### Name of organization / entity

Qazvin university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 1335 3061

##### Email address

nmoradimajd@qums.ac.ir

##### 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 address**Endodontic department, Qazvin school of dentistry,  
Qazvin university of medical sciences, Bahonar Blvd.**City**

Qazvin

**Email**

nimamajd@yahoo.com

**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

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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 address**Qazvin 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**

Nima Moradi Majd

**Position**

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*