

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Compariosn of the combination of premedication with ibuprofen plus inferior alveolar block plus buccal infiltration with inferior alveolar block plus buccal infiltration on anesthesia success of posterior mandibular teeth with irreversible pulpitis: A three blinded randomized clinical trial

Protocol summary

Summary

Achieving pulp anesthesia with irreversible pulpitis is difficult. This study evaluate whether nonsteroidal anti-inflammatory drugs assist local anesthesia. In a randomized double-blinded clinical trial, 100 patients (50 per group) with irreversible pulpitis will give placebo, 600 mg ibuprofen, 1 hour before local anesthesia. Each patient recorded their pain score on a visual analog scale before taking the medication, 15 minutes after anesthesia in response to a cold test, during access cavity preparation and during root canal instrumentation. No or mild pain at any stage was considered a success. Data will analyze by the chi-square test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611242016N7**
Registration date: **2016-12-20, 1395/09/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-20, 1395/09/30

Registrant information

Name

Masoud Parirokh

Name of organization / entity

Kerman University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2016-11-26, 1395/09/06

Expected recruitment end date

2017-01-25, 1395/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compariosn of the combination of premedication with ibuprofen plus inferior alveolar block plus buccal infiltration with inferior alveolar block plus buccal infiltration on anesthesia success of posterior mandibular teeth with irreversible pulpitis: A three blinded randomized clinical trial

Public title

Effect of different factors on the in-operative relief pain in root canal therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 or more than 18 years, no contraindications to taking either Ibuprofen (history of any allergic reaction to aspirin, NSAIDS, or Lidocaine with Epinephrine, nasal polyp, history of peptic ulcers or GI bleeding, pregnancy and lactation, renal or hepatic

disease), no history of GI disorders or ulcer, having no serious systemic disease. Exclusion criteria: no response to cold test, having sensitivity to percussion and palpation, having radiographic changes such as PDL widening, lack of vital pulp in coronal pulp chamber access cavity preparation, teeth with evidence of crack in their crown, having advanced periodontal disease, taking narcotic drugs or analgesic drugs in recent 24 hours before treatment.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The Ethic Committee of Kerman University of Medical Sciences

Street address

Vice-chancellor for Research, Building of kerman University of Medical Sciences, Tahmaseb-abad cross, Jihad Street

City

kerman

Postal code**Approval date**

2009-05-18, 1388/02/28

Ethics committee reference number

IR.KMU.REC.1395.13

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

Irreversible Pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

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

Response to cold test

Timepoint

Before taking drug, 1 hour after taking drug before anesthetic injection, after local anesthetic injection

Method of measurement

Cold spray

Secondary outcomes**1****Description**

In-operative pain

Timepoint

In access cavity preparation and during treatment

Method of measurement

Using Visual Analogue Scale (VAS)

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

Ibuprofen: 1 capsule of 600 mg, 1 hour before the local anesthetic injection

Category

Treatment - Drugs

2**Description**

placebo: 1 capsule contain 500 mg lactos mono hydrate, 1 hour before the local anesthetic injection

Category

Placebo

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

Endodontic Department, Kerman Dental School

Full name of responsible person

Dr. Masoud Parirokh

Street address

School of Dentistry, Shafa street

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology

Full name of responsible person

Dr. Abbas Pardakhti

Street address

Tahmasbabad cross road, Vice Chancellor for Research and Technology building

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Kerman

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 and Technology

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**

Vice Chancellor for Research and Technology

Full name of responsible person

Dr. Abbas Pardakhti

Position

Dean of the center

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Person responsible for updating data

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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