Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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

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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, Jahad Street

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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 injecyion

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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology
Full name of responsible person
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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
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

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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