

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of pretreatment with Ibuprofen, Indomethacin, and placebo on postoperative pain of mandibular molars with irreversible pulpitis.

Protocol summary

Summary

The objective of this study was to compare the effect of pretreatment with Ibuprofen, Indomethacin, and placebo on postoperative pain of mandibular molars with irreversible pulpitis. In this study 150 adult patients with a diagnosis of irreversible pulpitis in their mandibular molars referred to the Department of Endodontics of Kerman Dental School for treatment, were invited to participate. Pure powder of drugs were provided from drug manufactures and placed in similar capsules by pharmacologist in similar bottles which contain either 600 mg Ibuprofen, 75 mg Indomethacin, or placebo (500 mg lactos monohydrate). Postoperative pain was measured using the Heft-Parker Visual Analogue Scale (VAS) during 48 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811082016N3**

Registration date: **2010-02-20, 1388/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-02-20, 1388/12/01

Registrant information

Name

Masoud Parirokh

Name of organization / entity

Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

The Oral and Dental research Center and Research Committee of Kerman University of Medical Sciences

Expected recruitment start date

2009-05-18, 1388/02/28

Expected recruitment end date

2010-02-01, 1388/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of pretreatment with Ibuprofen, Indomethacin, and placebo on postoperative pain of mandibular molars with irreversible pulpitis.

Public title

Comparison the effect of pretreatment with Ibuprofen, Indomethacin, and placebo on postoperative pain of mandibular molars with irreversible pulpitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 18 years, no contraindications to taking either Ibuprofen or Indomethacin (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, the teeth with large restoration, teeth with evidence of crack in their crown, presence of periapical radiolucency, internal resorption or calcification, and also taking narcotic drugs or analgesic drugs in recent 12 hours before treatment.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **150**

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 Science

Street address

Vice-chancellor for Research, Kerman University of Medical Sciences, Tahmaseb-abad cross, Jahad Street,

City

Kerman

Postal code

76174

Approval date

2009-05-18, 1388/02/28

Ethics committee reference number

k/88/299

Health conditions studied

1

Description of health condition studied

Postoperative pain

ICD-10 code

K04

ICD-10 code description

Diseases of pulp and periapical tissues

Primary outcomes

1

Description

Postoperative pain

Timepoint

6, 12, 24, and 48 hours after the procedure

Method of measurement

Using Heft-Parker -Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

Indomethacin, 1 capsule of 75 mg, 1 hour before the local anesthetic injection)1 hour before injection of the local anesthetic

Category

Treatment - Drugs

3

Description

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

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and Dental Research center

Full name of responsible person

Dr.Masoud Parirokh

Street address

Endodontic Department, Kerman Dental School, Shafa Street

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oral and Dental Research Center and Vice-Chancellor for Research of Kerman University of Medical Sci

Full name of responsible person

Mrs. Hasani

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Vice-Chancellor for Research Building, Tahmasbabad cross, Jahad Street,

City

Kerman

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oral and Dental Research Center and Vice-Chancellor for Research of Kerman University of Medical Sci

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

Kerman University of Medical Sciences

Full name of responsible person

Nozar Nakhaee

Position

Resrach Manager/ Associate professor/PHD of epidemiology

Other areas of specialty/work
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Person responsible for scientific inquiries

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Position

Professor of endodontics

Other areas of specialty/work
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Postgraduate student

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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