Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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
KO4

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

Kerman

www.kmu.ac.ir

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

Street address
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
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Other areas of specialty/work

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Postgraduate student

Other areas of specialty/work

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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