Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of pretreatment with Ibuprofen, Indomethacin, and placebo on the success of inferior alveolar nerve block for teeth with irreversible pulpitis

Protocol summary

Summary

In this randomized double blind clinical trial 150 individuals referred to Department of Endodontics of Kerman Dental School for treatment, will receive either two different types of NSAIDs (600 mg Iboprofen or 75 mg Indometacin) or placebo (500 mg lactos monohydrate) in similar capsules, one hour before starting anesthesia in teeth with irreversible pulpitis and then the efficacy of the drugs on anesthesia success will be evaluated. Patient's pain intensity is recorded at three different times (preoperative, one hour after taking drug and before anesthetic injection, 15 minutes after IAN block and before operation) on the Heft–Parker Visual Analogue Scale (VAS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803192016N1**
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

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

Expected recruitment start date

2009-09-11, 1388/06/20

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 the success of inferior alveolar nerve block for teeth with irreversible pulpitis

Public title

Comparison the effect of pretreatment with Ibuprofen, Indomethacin, and placebo on the success of inferior alveolar nerve block for teeth 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, teeth with evidence of crack in their crown, having advanced periodontal disease, taking narcotic drugs or analgesic drugs in recent 12 hours before treatment.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **150**

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
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

City
Kerman

Postal code
76174

Approval date
2009-05-18, 1388/02/28

Ethics committee reference number
KA/88-05

Health conditions studied

1

Description of health condition studied
Teeth with irreversible pulpitis

ICD-10 code
K04

ICD-10 code description
Diseases of pulp and periapical tissues

Primary outcomes

1

Description
Response to cold test

Timepoint
1 hour after taking drug

Method of measurement
using cold spray

Secondary outcomes

1

Description
pain

Timepoint
After injection of local anesthesia and during treatment

Method of measurement
using visual analoug scale (VAS)

Intervention groups

1

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

Category
Treatment - Drugs

2

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

Category
Treatment - Drugs

3

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
Oral and Dental Research center

Full name of responsible person
Dr.Masoud Parirokh

Street address

Endodontic Department, Kerman Dental School, Shafa Street

City
Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oral and Dental Resrach Center and Vice-Chancellor for Research, Kerman University of Medical Scienc

Full name of responsible person
Ms. Hasani

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

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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
Oral and Dental Resrach Center and Vice-Chancellor for Research, Kerman University of Medical Scienc

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
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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