Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of prophylactic use of Sulindac in comparison with Ibuprofen on post-operative endodontic pain

Protocol summary

Summary

In this clinical trial study, 48 patients with average age of 25-50 years who were medically healthy were selected. The study was done on vital anterior single root canal teeth with severe decay and spontaneous pain at range of 0-30 in visual analogue scale (VAS) but without periapical lesion (radiographically), swelling, or fistula. The patients were allocated into three groups matched for sex to receive 400 mg Ibuprofen (Aria, Tehran, Iran), 200 mg Sulindac (Merksharp & dohm, USA) or placebo one capsule as prophylaxis 1 hour before treatment. The drugs were prepared identically as capsules. All patients will receive standard treatments with identical method. In addition, the patients were given two acetaminophen codeine 300/10 mg tablets for severe continuous post-operative pain. Intensity of pain is recorded by the patients through Visual Analogue Scale 6, 12, 24, 48, and 72 hours after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809222847N1**
Registration date: **2010-06-22, 1389/04/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-06-22, 1389/04/01

Registrant information

Name

Mohammad Mahdi Yaghooti Khorasani

Name of organization / entity

Dental School, Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of prophylactic use of Sulindac in comparison with Ibuprofen on post-operative endodontic pain

Public title

Efficacy of prophylactic use of Sulindac in comparison with Ibuprofen on post-operative endodontic pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of vital anterior single root canal teeth with severe decay and spontaneous pain at range of 0-30 in VAS, Patient who are medically healthy, positive responses to pulpal tests (thermal testes and pulp tester) Exclusion criteria: Presence of periapical lesion (in radiography), swelling, or fistula, contraindications to study drug consumption, receiving analgesics 12 hours before the treatment

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

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

Ethical committee of Rafsanjan University of Medical Sciences

Street address

Rafsanjan University of Medical Sciences, Imam Ali Blvd.

City

Rafsanjan

Postal code

7717933777

Approval date

2010-05-11, 1389/02/21

Ethics committee reference number

9/20/223

Health conditions studied

1

Description of health condition studied

post-operative endodontic pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

post-operative pain

Timepoint

6, 12, 24, 48, & 72 hours after treatment

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

400mg Ibuprofen (Aria,Tehran,Iran) one hour before the treatment

Category

Treatment - Drugs

2

Description

Placebo, one capsule one hour before the treatment

Category

Placebo

3

Description

The third group were given one capsule containing 200 mg Sulindac(Merksharp&dohm,USA) before the treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental office of Dr Mahmud Motamedinejad

Full name of responsible person

Dr Mahmud Motamedinejad

Street address

City

Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Ali Shamsizade

Street address

Rafsanjan University of Medical Sciences, Imam Ali BLV

City

Rafsanjan

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan University of Medical Sciences
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
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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