

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 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, Rafsanjan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3428 0031

##### Email address

dr.yaghooti@goums.ac.ir

##### 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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Dental school, Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Dr Mohammad Mahdi Yaghooti Khorasani  
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Assistant professor  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*