

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### **A comparative study of analgesic effects of Ibuprofen, Novafen, Mefenamic acid and Celecoxib in relieving pain of symptomatic pulpitis before emergency endodontic intervention**

#### **Protocol summary**

##### **Study aim**

A comparative study of analgesic effects of Ibuprofen, Novafen, Mefenamic acid and Celecoxib in relieving pain of symptomatic pulpitis before emergency endodontic intervention

##### **Design**

In this study, 120 patients selected from the Department of Endodontics, Faculty of Dentistry, Kerman, who have been diagnosed with symptomatic pulpitis and had moderate to severe pain (VAS above 3), will be able to take immediate medical treatment in their department. There are no patients with any drug interactions or systemic diseases. People are divided into 4 groups of 30 people who give each group a specific home

##### **Settings and conduct**

This study was conducted to compare Ibuprofen, Naufafen, Mefenamic acid and Celecoxib with dental pain relief in symptomatic pulpitis patients before endodontic treatment. A total of 120 patients referred to the endodontics department of Kerman dental school, The root that has been diagnosed with symptomatic pulp is given that the VAS is above 3 and have the conditions for entry into the study, will be selected. The patients are divided into 4 groups of 30, each of whom has a specific type of housing that has the powder of the analgesics in the same capsule so that both the designers and the patients will be unaware of the type of drug. Also, the code The drug groups will be opened and identified after the statistical review. The statistician will also be aware of the type of drug and the groups studied.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: The patient has an irreversible acute pulpitis, diagnosed by a dentist; Lack of medical problem (20) (such as history of stroke or heart failure, heart failure, blood pressure, asthma, nasal polyps, liver or kidney disease, gastric ulcer, systemic lupus, blood clotting problems, etc.); Access to the patient; Patients

without oral and history of corticosteroid susceptibility are nonsteroidal inflammation; The teeth should be permanent and apex; Failure to quickly deal with endodontic emergencies; Patient Satisfaction and Compliance Form Completion; Do not be pregnant, pregnant or breastfeeding. Exit criteria: Patients who have received housing for up to 6 hours; Patients who for any reason prohibit the use of the drugs studied.

##### **Intervention groups**

In this study, we divided the patients into four groups, which divided the first group of ibuprofen, the second group of naufafen, into the third group of mefenamic acid, and the fourth group of celecoxib, to determine the most effective drug in reducing the pain of patients with severe irreversible pulpitis.

##### **Main outcome variables**

The results of our research can help the dentist to control and reduce the pain and discomfort to the patients due to the severity of the pain and the effects of various types of analgesics (ibuprofen, naufafen, mefenamic acid and celecoxib). Has an irreversible acute pulpitis in the pre-endodontic treatment.

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20171109037332N1**

Registration date: **2018-01-06, 1396/10/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-06, 1396/10/16**

Update count: **0**

##### **Registration date**

2018-01-06, 1396/10/16

##### **Registrant information**

**Name**

**Name of organization / entity****Country**

Iran (Islamic Republic of)

**Phone**

+98 32118022

**Email address**

h.kamyabi1244@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source****Expected recruitment start date**

2017-12-01, 1396/09/10

**Expected recruitment end date**

2019-01-20, 1397/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparative study of analgesic effects of Ibuprofen, Novafen, Mefenamic acid and Celecoxib in relieving pain of symptomatic pulpitis before emergency endodontic intervention

**Public title**

Comparison of the effect of Ibuprofen, Naufafen, Mefenamic acid and Celecoxib on the improvement of dental pain in the stage before the endodontic emergencies

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patient has an irreversible acute pulpitis, diagnosed by a dentist; Lack of medical problem (20) (such as history of stroke or heart failure, heart failure, blood pressure, asthma, nasal polyps, liver or kidney disease, gastric ulcer, systemic lupus, blood clotting problems, etc.); Access to the patient; Patients without oral disease and history of corticosteroid susceptibility are nonsteroidal inflammation; The teeth should be permanent with closed apex; Failure to quickly deal with endodontic emergencies; Patient satisfaction and compliance form completion

**Exclusion criteria:**

Patients who have received a home for up to 6 hours before; Patients who for any reason prohibit the use of the drugs studied.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator

- Data analyser

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In each group, the company will take 30 pills of powdered detergents and will be placed inside a blank capsule. So that both the project executives and the patients will be unaware of the type of medication. Also, the code of the drug groups will be revealed and determined after the statistical review. The statistician will also be aware of the type of medication and the groups being studied.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

**Street address**

Blvd.Heft Gardens Alavi-Pardis University of Medical Sciences

**City**

kerman

**Province**

Kerman

**Postal code**

7616913555

**Approval date**

2017-11-17, 1396/08/26

**Ethics committee reference number**

IR.KMU.REC.1395.1002

**Health conditions studied****1****Description of health condition studied**

symptomatic pulpitis

**ICD-10 code**

K04.0

**ICD-10 code description**

pulpitis

## Primary outcomes

### 1

#### Description

Intensity of pain

#### Timepoint

Measure the severity of pain at the beginning of the study (before the intervention) and 1 hour after taking the drug

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention group: Ibuprofen 400 once

#### Category

Other

### 2

#### Description

Second intervention group: Novafer once, containing 325 mg of acetaminophen, 40 mg of caffeine and 200 mg of ibuprofen.

#### Category

Other

### 3

#### Description

Third intervention group: Mefenamic acid 250 once

#### Category

Other

### 4

#### Description

Fourth intervention group: Celecoxib 200 once

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Dentistry, Kerman University of Medical Sciences

##### Full name of responsible person

rahim fereidooni

##### Street address

Shafa St., Faculty of Dentistry

##### City

kerman

##### Province

Kerman

##### Postal code

7618759689

##### Phone

+98 34 3211 9028

##### Email

endo\_kerman@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

abbas pardakhti

##### Street address

Boulevard of Al-Awli Gardens, Kerman University of Medical Sciences

##### City

kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 34 3132 5700

##### Email

endo\_kerman@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kerman University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Homa kamyabi

##### Position

Dentistry student

##### Latest degree

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

Shafa St., School of Dentistry

**City**

kerman

**Province**

Kerman

**Postal code**

7618759689

**Phone**

+98 34 3211 9028

**Fax****Email**

h.kamyabi1244@gmail.com

**Web page address**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

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**Postal code**

7618759689

**Phone**

+98 34 3211 9028

**Fax****Email**

h.kamyabi1244@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

arash shahravan

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Shafa St., Faculty of Dentistry

**City**

kerman

**Province**

Kerman

**Postal code**

7618759689

**Phone**

+34 32119028

**Fax****Email**

arashahravan@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Homa kamyabi

**Position**

Dentistry student

**Latest degree****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The total potential data can be shared after unidentifiable people are removed,

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Data will only be available to researchers in academia and academia

**Under which criteria data/document could be used**

There are no other conditions for using data

**From where data/document is obtainable**

Homa Kamyabi, h.kamyabi1244@gmail.com Dr Rahim Fereidooni, rahim.fereidooni71@yahoo.com Dr Arash Shahravan, arashahravan@gmail.com

**What processes are involved for a request to access data/document**

The applicant sends emails to each researcher and their introduction and reasons for requesting data at the latest after one month of data

**Comments**