

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Efficacy of pretreatment by Celecoxib and Gelofen on post endodontic pain

#### Protocol summary

##### Summary

This randomized double blind Clinical trial study was accomplished to compare the analgesic effect of Celecoxib 200mg and Gelofen 400 mg on post endodontic pain. Ninety patients in 3 groups (30 patients in each group) recruited. In a double blind study, capsules of Celecoxib, Gelofen and Placebo were randomly prescribed to the patients 1 hour before treatment. Patient reported visual analog Scale rating of pain intensity, were used upon initial clinical presentation and patients were asked to record their pain at 4, 8, 12, 24 and 48 hours after intervention. Inclusion criteria were: age between 18 to 65; and having vital premolars of mandible or maxilla without any pre apical lesion and exclusion criteria were: pregnancy; allergy to sulfonamide and NSAIDs; history of asthma related to nasal polyp; history of chronic using of analgesics; alcohol using; uncontrollable high blood pressure; diabetes mellitus; systemic disease and not using analgesic medicine 12 hours before study. Primary outcome of the study was the pain after surgery and measured by pain visual analogous scale.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201106306926N1**  
Registration date: **2011-07-23, 1390/05/01**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-07-23, 1390/05/01

##### Registrant information

**Name**

Shaghayegh Nooribayat

##### Name of organization / entity

Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 911 220 0198

##### Email address

sh.nooribayat@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Science

##### Expected recruitment start date

2009-07-27, 1388/05/05

##### Expected recruitment end date

2009-12-27, 1388/10/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of pretreatment by Celecoxib and Gelofen on post endodontic pain

##### Public title

Efficacy of pretreatment by medicines on post endodontic pain

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 65; and having vital premolars of mandible or maxilla without any pre apical lesion Exclusion criteria: pregnancy; allergy to sulfonamide and NSAIDs; history of asthma related to nasal polyp; history of chronic using of analgesics; alcohol using; uncontrollable high blood pressure;

diabetes mellitus; systemic disease and not using analgesic medicine 12 hours before study

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **90**

### 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

Shiraz University of Medical Sciences Ethics Committee

##### Street address

The Office of Research, 7th floor, Main building of Shiraz University of Medical Sciences, Zand street

##### City

Shiraz

##### Postal code

2359317711

##### Approval date

2009-06-26, 1388/04/05

##### Ethics committee reference number

705

## Health conditions studied

### 1

#### Description of health condition studied

Endodontic pain

#### ICD-10 code

K08.9

#### ICD-10 code description

Disorder of teeth and supporting structures, unspecified

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

4, 8, 12, 24 and 48 hours after intervention

#### Method of measurement

VAS scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Gelofena as capsule 400 mg, oral, one dose 2 hours before starting the treatment

#### Category

Treatment - Drugs

### 2

#### Description

placebo as capsule, oral one dose 2 hours before starting the treatment

#### Category

Placebo

### 3

#### Description

Celecoxib as capsule 200mg, per oral one dose 2 hours before starting the treatment

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Endodontics department, Dental Faculty, Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Mehdi Mirzaie

##### Street address

Resident of radiology, Babol Denatal Faculty

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

**Full name of responsible person**

**Street address**

The Office for Research, 7th floor, Main building of Shiraz University of Medical Sciences, Zand street

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Shiraz 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**

**Name of organization / entity**

Dental student of Research Committee, Dental Faculty, Babol University of Medical Sciences

**Full name of responsible person**

Shaghayegh Nooribayat

**Position**

Student of Dentistry, Research Committee, Dental Faculty, Babol University of Medical Sciences

**Other areas of specialty/work**

**Street address**

Research Committee, Dental Faculty, Babol University of Medical Sciences

**City**

Babol

**Postal code**

**Phone**

+98 12 1225 1451

**Fax**

**Email**

dr.sh.noori@gmail.com; sh.nooribayat@mubabol.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Dental Faculty, Babol University of Medical Sciences

**Full name of responsible person**

Shaghayegh Nooribayat

**Position**

Student of Dentistry

**Other areas of specialty/work**

**Street address**

Research Committee, Dental Faculty, Babol University of Medical Sciences

**City**

Babol

**Postal code**

**Phone**

+98 12 1225 1451

**Fax**

**Email**

sh.nooribayat@mubabol.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Research Committee, Dental Faculty, Babol University of Medical Sciences

**Full name of responsible person**

Shaghayegh Nooribayat

**Position**

Student of Dentistry

**Other areas of specialty/work**

**Street address**

Research Committee, Dental Faculty, Babol University of Medical Sciences

**City**

Babol

**Postal code**

**Phone**

+98 12 1225 1451

**Fax**

**Email**

sh.nooribayat@mubabol.ac.ir

**Web page address**

## 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*