

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Prophylactic effect of Novafen and Gelofen on post endodontic treatments pain decrement

#### Protocol summary

##### Summary

This study was performed to evaluate prophylactic effect of Novafen and Gelofen on post endodontic treatments pain decrement. Patients who received treatment in Endodontic Dentistry Clinic, Dentistry School of Babol University Of Medical Sciences between the years of 2013-2014 were participated in this study. Inclusion criteria included: patients' contentment and their ability for completing the forms. Exclusion criteria included: history of systemic disease; hypersensitivity to NSAIDs; and history of chronic use of analgesics or sedatives. The sample size of 60 was considered. One hour before treatment; 2 capsules as placebo to the patients in control group, 2 200 mg Novafen capsules to Novafen group, and 2 200 mg Gelofen capsules to Gelofen group; were prescribed orally in order to pain decrement after the treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014041316973N2**

Registration date: **2014-10-04, 1393/07/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-10-04, 1393/07/12

##### Registrant information

###### Name

Mohammad Kashefinejad

###### Name of organization / entity

Faculty of Dentistry, Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 1229 1408

###### Email address

m.kashefi@mubabol.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Babol University of Medical Sciences

##### Expected recruitment start date

2013-09-23, 1392/07/01

##### Expected recruitment end date

2014-01-20, 1392/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Prophylactic effect of Novafen and Gelofen on post endodontic treatments pain decrement

##### Public title

evaluation of the effect of Novafen and Gelofen in post canal treatment pain decrement

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1.The patient should be able to read , understand and complete the consent form; 2.Patient's consent form has been completed; 3.Teeth with a live pulp that do not have a peri-apical lesion should have been evaluated. Exclusion criteria : 1.Pregnancy; 2.Hypersensitivity to NSAIDs and Sulfonamides; 3.History of asthma associated with nasal polyps; 4.History of chronic use of analgesics or sedatives; 5.Alcohol abuse; 6.Patients with uncontrolled hypertension; 7.Diabetes mellitus; 8.Renal disease, CNS disease, heart disease

and liver dysfunction; 9.Cancer or major anomalies confirmed by clinical examinations or laboratory findings; 10.Aged less than 18 and more than 65; 11.Pregnancy or breastfeeding; 12.Analgesic use less than 12 hours to the beginning of the study.

#### Age

From **18 years** old to **64 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### 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

Babol University of Medical Sciences

##### Street address

Ganj Afrooz Ave. University Sq.

##### City

Babol

##### Postal code

4717641376

#### Approval date

2013-12-23, 1392/10/02

#### Ethics committee reference number

923698

## Health conditions studied

### 1

#### Description of health condition studied

Pharmacokinetics

#### ICD-10 code

K04.9

#### ICD-10 code description

Other and unspecified diseases of pulp and periapical tissues

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

One hour before treatment

#### Method of measurement

4,8,12,24,48

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In control group : Prescribed 2 capsules orally 1 hour before treatment as placebo

#### Category

Other

### 2

#### Description

Novafen group: Prescribed 2 200 mg capsules orally 1 hour before treatment

#### Category

Treatment - Drugs

### 3

#### Description

Gelofen group: Prescribed 2 200 mg capsules orally 1 hour before treatment

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Endodontics, Dentistry School, Babol University of Medical Sciences

##### Full name of responsible person

##### Street address

Ganj Afrooze Ave. University Sq.

##### City

Babol

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Ali Bijani

**Street address**

Ganje Afrooz Ave. University SQ.

**City**

Babol

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Babol 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**

Babol Univesity Of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Kashefi Nejad

**Position**

PhD in Endodontics

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**Fax****Email****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*