Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 capsulles as placebo to the patients in control group, 2 200 mg Novafen capsulles to Novafen group, and 2 200 mg Gelofen capsulles 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

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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 befor treatment

Category
Treatment - Drugs

3

Description
Gelofen group: Prescribed 2 200 mg capsules orally 1 hour befor 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
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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