Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 200mgand 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 Univercity of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz Univecity 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 houres before starting the treatment

Category
Treatment - Drugs

2

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

Category
Placebo

3

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

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endodintics 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

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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