Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of prophylactic effect of Ibuprofen and Novafen with placebo on pain relief in patients requiring endodontic treatment

Protocol summary

Summary

Objectives: Comparison of prophylactic effect of Ibuprofen and Novafen on pain relief after endodontic treatment in patients referred to Salamat clinic of Qom. Design: Randomized, double blinded, placebo controlled, single center, phase 4 trial. Study population: patients requiring endodontic treatment. The inclusion criteria: Age range of 18 to 65 years old; having teeth with alive pulps and no periapical lesion; moderate to severe dental pain at reception (VAS>4). The exclusion criteria: Pregnancy; lactation; history of allergy to NSAID or sulfonamides; history of asthma; chronic use of analgesic; alcohol consumption; having systemic diseases; having cancer or severe abnormalities; use of any analgesic during 12 hours before starting intervention; current smoker. Sample size: 96. Intervention: Novafen, capsule 200 mg oral, once, 1 hour before root canal therapy. Ibuprofen, capsule 400 mg oral, once, 1 hour before root canal therapy. Placebo, capsule oral, once, 1 hour before root canal therapy. Outcome: severity of dental pain, number of analgesic used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031032984N1**
Registration date: **2017-07-01, 1396/04/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-01, 1396/04/10

Registrant information

Name

Atieh sadat Rezaei

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 762 0801

Email address

sgholizade@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-05-24, 1396/03/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prophylactic effect of Ibuprofen and Novafen with placebo on pain relief in patients requiring endodontic treatment

Public title

Effect of Ibuprofen and Novafen on pain relief after endodontic treatment

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: Age range of 18 to 65 years old; having teeth with alive pulps and no periapical lesion; moderate to severe dental pain at reception (VAS>4)
The exclusion criteria: Pregnancy; lactation; history of allergy to NSAID or sulfonamides; history of asthma;

chronic use of analgesic; alcohol consumption; having systemic diseases; having cancer or severe abnormalities; use of any analgesic during 12 hours before starting intervention; current smoker

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **96**

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
Oom University of Medical Sciences

Street address
Qom University of Medical Sciences, Saheli street, Qom

City
Qom

Postal code
3713649373

Approval date
2016-08-13, 1395/05/23

Ethics committee reference number
IR.MUQ.REC.1395.81

Health conditions studied

1

Description of health condition studied
Relation of prophylactic effect of Ibuprofen and Novafen on pain relief after endodontic treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Severity of dental Pain

Timepoint
Before treatment, 6 hour after treatment, 12 hour after treatment, 24 hour after treatment, 48 hour after treatment

Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Number of analgesic used

Timepoint
24 hour after treatment, 48 hour after treatment

Method of measurement
Patients report

Intervention groups

1

Description
Novafen, capsule 200 mg oral, once, 1 hour before root canal therapy

Category
Treatment - Drugs

2

Description
Ibuprofen, capsule 400 mg oral, once, 1 hour before root canal therapy

Category
Treatment - Drugs

3

Description
Placebo, capsule oral, once, 1 hour before root canal therapy

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Salamat clinic, Qom University of Medical Sciences

Full name of responsible person

Street address

City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qom University of Medical Sciences
Full name of responsible person
Dr Hossein Saghafi
Street address
Number 83, Alley 4, Alley 1.1, Safashahr street
City
Qom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qom 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
Qom University of Medical Sciences
Full name of responsible person
Atieh sadat Rezaei
Position
doctor student
Other areas of specialty/work
Street address
Salamat Clinic, Bajak street, Qom
City
Qom
Postal code
Phone
+98 25 3612 2053
Fax
Email
amir.sad313@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qom University of Medical Sciences
Full name of responsible person
Sedighe Gholizade
Position
Medical Doctor
Other areas of specialty/work
Street address
Qom University of Medical Sciences, Saheli street, Qom
City
Qom
Postal code
Phone
+98 25 3770 0094
Fax
Email
sgholizade@muq.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Qom University of Medical Sciences
Full name of responsible person
Atieh sadat Rezaei
Position
Doctor student
Other areas of specialty/work
Street address
Salamat Clinic, Bajak street, Qom
City
Qom
Postal code
3719964797
Phone
+98 25 3612 2053
Fax
Email
amir.sad313@gmail.com
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