

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

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Name of organization / entity

Qom University of Medical Sciences

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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

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Full name of responsible person

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Position

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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