

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Indomethacin and Ibuprofen on postoperative Endodontic pain in referring patients to the Endodontic department with dental pain

Protocol summary

Summary

In this clinical trial study mandibular molars with irreversible pulpitis were endodontically treated in 66. The medicines were prepared similarly in the form of capsules containing 400 mg Ibuprofen (group A), 25 mg indomethacin (group B) and placebo (group C). The patients were given one capsule 1 h before the start of treatment. Patients recorded their pain measured by a visual analogue scale (VAS) at medication time, during treatment and 8, 12 and 24 h after treatment. Ibuprofen and indomethacin significantly reduced the postoperative pain in comparison with placebo during treatment and 8 h after treatment; however, there was no significant difference between them at 12 and 24 h after treatment. Premedication with ibuprofen and indomethacin can effectively control the postoperative pain; less side effect and more analgesic influence of ibuprofen make it the superior choice

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010712048N1**

Registration date: **2016-01-05, 1394/10/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-05, 1394/10/15

Registrant information

Name

Zeinab Hamzeheil

Name of organization / entity

Shahid Sadoughi University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1625 6975

Email address

z.hamzeheil@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University Of Medical Sciences

Expected recruitment start date

2011-07-20, 1390/04/29

Expected recruitment end date

2012-02-14, 1390/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Indomethacin and Ibuprofen on postoperative Endodontic pain in referring patients to the Endodontic department with dental pain

Public title

Effect of premedication with Indomethacin and Ibuprofen on postoperative Endodontic pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with first and second molars with irreversible pulpitis having normal radiographic view without any lesion or fistula; exhibit a long response to the pulp tester and cold testing exclusion criteria: individual younger than 18 years and older than 50 years; Consumption of analgesic drug 12 hours before treatment; Allergic history to NSAIDs or Lidocaine with 1/80000 Epinephrine; patients with systemic disease; Take contraindicated drugs with NSAIDs; Pregnancy and

nursing: teeth with periapical lesion or acute periapical abscess: aggressive periodontal disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **66**

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

Shahid Sadoughi University of Medical Science

Street address

Central Department of University, Bahonar Square

City

Yazd

Postal code

Approval date

2009-08-15, 1388/05/24

Ethics committee reference number

۱۷/۱/۴۶۲۱۰/ب

Health conditions studied

1

Description of health condition studied

Effect of premedication with Indomethacin and Ibuprofen on postoperative endodontic pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The analgesic effect

Timepoint

8,12,24 hours after treatment

Method of measurement

By Visual Analogus Scale(VAS)

Secondary outcomes

1

Description

Gastritis

Timepoint

After treatment

Method of measurement

Grade (low, intermediate, high)

Intervention groups

1

Description

Indomethacin/25mg/capsule/1 hours before treatment

Category

Treatment - Drugs

2

Description

Ibuprofen/400mg/capsule/1 hours before treatment

Category

Treatment - Other

3

Description

Placebo/capsule/1 hours before treatment

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School

Full name of responsible person

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Fatemeh Ezodini

Street address

Yazd Shahid Sadoughi University of Medical Sciences,
Dental School, Fazaye sabz Crossroad, Dahe-fajr Blv,
Yazd, Iran

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd Shahid Sadoughi 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

Shahid Sadoughi University of Medical Science

Full name of responsible person

Zeinab Hamzeheil

Position

Dentist

Other areas of specialty/work

Street address

Fzaye Sabz, Dental School, Yazd, Iran

City

Yazd

Postal code

Phone

+98 35 1625 6975

Fax

Email

n_hamzeiil@yahoo.com; z.hamzeheil@ssu.ac

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Science

Full name of responsible person

Fatemeh Mokhtari

Position

Endodontics

Other areas of specialty/work

Street address

Fazaye Sabz, Dental School, Yazd, Iran

City

Yazd

Postal code

Phone

+98 35 1625 6975

Fax

Email

mokhtari.f.d@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Science

Full name of responsible person

Zeinab Hamzeheil

Position

Dentist

Other areas of specialty/work

Street address

Fazaye Sabz, Dental School, Yazd, Iran

City

Yazd

Postal code

Phone

+98 35 1625 6975

Fax

Email

n_hamzeiil@yahoo.com; z.hamzeheil@ssu.ac

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