Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 NSATDs 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
پ/۱۷/۱/۴۶۲۱۰

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 befor treatment

Category
Treatment - Drugs

2

Description
Ibuprofen/400mg/capsule/1 hours befor 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

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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