Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of using ibuprofen and netonal drugs before root canal treatment on the pain after treatment in teeth with irreversible pulpitis

Protocol summary

Study aim

Determining the effect of using ibuprofen and netonal drugs before root canal treatment on the pain after treatment in teeth with irreversible pulpitis

Design

A clinical trial type study with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients, for randomization, each person was assigned a number using the Random Allocation software and the patients based on that Number were placed in one of the three treatment groups of ibuprofen, netonal or placebo.

Settings and conduct

. Place: Department of Endodontic Treatment, Faculty of Dentistry, Isfahan University of Medical Sciences, Iran. Patients completed the pain scales. For intervention group 1, ibuprofen, intervention group 2, netonal and control group, placebo were prescribed. Anesthesia was administered and 10 minutes later, pain score was recorded. Filing channels were done. Pain was recorded immediately and 8, 12 and 24 hours after the treatment. The intervention was blinded to the patients and researchers.

Participants/Inclusion and exclusion criteria

Inclusion: patients with irreversible pulpitis of mandibular first or second molar teeth, spontaneous tooth pain based on VAS or Wong-Baker shape scale at least 30 mm, normal dental radiography, no lesion or sinus tract, long response to electrical test Pulp and cold test with a cotton roll cooled by endo- ice Exclusion: use of analgesics in the last 12 hours, long-term use of drugs that interfere with non-steroidal anti-inflammatory drugs, sensitivity to non-steroidal anti-inflammatory drugs or lidocaine, chronic systemic disease, pregnant mothers, teeth with periapical lesions. and chronic periapical abscess, patients with periodontal invasion, patients with irreparable teeth or with previous restorations.

Intervention groups

Intervention1: Ibuprofen Intervention 2: Netonal Placebo: Control

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230313057710N2**
Registration date: **2023-07-02, 1402/04/11**
Registration timing: **retrospective**

Last update: **2023-07-02, 1402/04/11**
Update count: **0**

Registration date

2023-07-02, 1402/04/11

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-03, 1398/04/12

Expected recruitment end date

2019-11-01, 1398/08/10

Actual recruitment start date

2019-07-03, 1398/04/12

Actual recruitment end date

2019-11-01, 1398/08/10

Trial completion date

2019-11-01, 1398/08/10

Scientific title

Investigating the effect of using ibuprofen and netonal drugs before root canal treatment on the pain after treatment in teeth with irreversible pulpitis

Public title

Investigating the effect of using ibuprofen and netonal drugs before root canal treatment on the pain after treatment in teeth with irreversible pulpitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with irreversible pulpitis of mandibular first or second molar teeth who have been referred for treatment, The spontaneous tooth pain, according to the Visual Analogue Scale or Wong-Baker figure scale, is at least 30 mm, The radiographic appearance of the teeth in these patients is normal, Do not have lesion or a sinus tract (chronic periapical abscess), Give a long response to the electrical pulp test (EPT) and the cold test with a cotton roll cooled by endo-ice.

Exclusion criteria:

Patients who have used any sedative in the last 12 hours, Patients who have used long-term drugs that interact with NSAIDs, Patients who are allergic to NSAIDs or lidocaine or have systemic problems, Pregnant mothers, Teeth with lesions Periapical and chronic periapical abscess, Patients with aggressive periodontal disease, Patients with unrepairable or previously repaired cavities, Patients who have pain in more than one tooth.

Age

From **10 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were selected by convenience sampling method. Block randomization method was used for random assignment to groups. Random Allocation Software was used for block randomization. On the first page of this software, the number of groups and sample size were entered. On the next page of the software, it was determined how many blocks should be. Blocks with a length of six cells were selected. In the next step, the software created a list of numbers along with grouping. A number was assigned to each patient in the order of entry, and based on that number, the patients were assigned to one of the three treatment groups: ibuprofen, netonal, or placebo in one of the blocks. This action continued until 20 people were entered in each group and 60 people were selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

All drugs were similar in shape, color and size. In order to simulate the drugs, the tablets were divided into small pieces and then they were put into capsules of the same color and the same size. The placebo substance (sugar) was placed inside the same type of capsules without any need to change.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-06-26, 1398/04/05

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.214

Health conditions studied

1

Description of health condition studied

Pulpits

ICD-10 code

k00-k14

ICD-10 code description

Diseases of oral cavity, salivary glands and jaws

Primary outcomes

1

Description
Pulpits Pain
Timepoint
Before treatment, immediately after treatment and 8, 12 and 24 hours after treatment
Method of measurement
Using Visual analogue scale و Wong-Baker Ғigure scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Iboprofen tablet: Before the intervention, patients completed the demographic questionnaire, visual analog pain scale, and Wong-Baker shape scale. Intervention group 1 was prescribed a number of 400 mg ibuprofen tablets of Aria Pharmaceutical Company, 30 minutes before endodontic treatment of irreversible pulpitis. Then anesthesia was injected to treat the lower mandibular nerve with two carpools of 1.8 ml lidocaine 2% with epinephrine 1:80000. 10 minutes after anesthesia, pain was recorded by asking the patients. After preparation of the access cavity, the tooth was isolated using a rubber band and the length was determined using radiography information. Filing and flaring of channels was done using step-back method. Normal saline and 2% hypochlorid were used to wash inside the canal. The canals were dried using a paper cone and the canals were filled using gutta percha and ZOE sealer and lateral compression technique at a distance of 0.5 to 1 mm from the radiographic apex. Again, the pain intensity of the patients was recorded. Next, the patients were asked to record their pain 8, 12 and 24 hours after the treatment.
Category
Treatment - Drugs

2

Description
Intervention group2: Natonal tablet: Before the intervention, patients completed a demographic questionnaire, visual analog pain scale, and Wong-Baker shape scale. Intervention group 2 was prescribed a number of 400 mg Natonal tablets of Barij Essance pharmaceutical company, 30 minutes before endodontic treatment of irreversible pulpitis. Then anesthesia was injected to treat the lower mandibular nerve with two carpools of 1.8 ml lidocaine 2% with epinephrine 1:80000. 10 minutes after anesthesia, pain was recorded by asking the patients. After preparing the tooth access cavity, it was isolated using a rubber band and the length was determined using radiographic information. Filing and flaring of channels was done using step-back method. Normal saline and 2% hypochlorid were used to wash inside the canal. The canals were dried using a paper cone and the canals were filled using gutta percha and ZOE sealer and lateral compression technique at a distance of 0.5 to 1 mm from the radiographic apex. Again, the pain intensity of the patients was recorded. Next, the patients were asked to record their pain 8, 12 and 24 hours after the treatment.
Category
Treatment - Drugs

3

Description
Control group: Placebo: Control group: Placebo: Before the intervention, patients completed the demographic questionnaire, visual analog pain scale, and Wong-Baker shape scale. Intervention group 2 was prescribed a number of placebo capsules containing sugar, 30 minutes before endodontic treatment of irreversible pulpitis. Then anesthesia was injected to treat the lower mandibular nerve with two carpools of 1.8 ml lidocaine 2% with epinephrine 1:80000. 10 minutes after anesthesia, pain was recorded by asking the patients. After preparing the tooth access cavity, it was isolated using a rubber band and the length was determined using radiographic information. Filing and flaring of channels was done using step-back method. Normal saline and 2% hypochlorite were used to wash inside the canal. The canals were dried using a paper cone and the canals were filled using gutta percha and ZOE sealer and lateral compression technique at a distance of 0.5 to 1 mm from the radiographic apex. Again, the pain intensity of the patients was recorded. Next, the patients were asked to record their pain 8, 12 and 24 hours after the treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
80
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Zahra Khosravani
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Resident in Endodontics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available