Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparasion of the Effect of Diclofenac Sodium and Ketorolak on Post Endodontic Pain in Mandibular first Molars with Symptomatic Irreversible Pulpitis

Protocol summary

Study aim
Comparison of the Effect of Diclofenac Sodium and Ketorolac on Post Endodontic Pain in Mandibular first Molars with Symptomatic Irreversible Pulpitis

Design
A randomised, double blinded clinical trial with a parallel group design of 45 patients. A random number table was used for randomization.

Settings and conduct
A number of 45 patients with inclusion criteria who referred to Alborz Dental Clinic of Urmia or Dental Office.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 18 to 60 years with mandibular first molars with irreversible pulpitis require endodontic treatment. Non-entry conditions: Any drug interactions with the drugs in this study and a history of systemic diseases

Intervention groups
Intervention group 1: Patients receiving diclofenac sodium Intervention group 2: Patients receiving ketorolac Control group: patients receiving placebo

Main outcome variables
Pain intensity, duration of analgesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180513039638N1**
Registration date: **2021-04-04, 1400/01/15**
Registration timing: **prospective**

Last update: **2021-04-04, 1400/01/15**
Update count: **0**

Registration date
2021-04-04, 1400/01/15

Registrant information
Name
Amir Ardalan Abdollahi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-08, 1400/01/19

Expected recruitment end date
2021-08-10, 1400/05/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparasion of the Effect of Diclofenac Sodium and Ketorolak on Post Endodontic Pain in Mandibular first Molars with Symptomatic Irreversible Pulpitis

Public title
Evaluation of analgesic effects of diclofenac sodium and ketorolac in root canal therapy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patient who requires root canal treatment of the first mandibular molars with irreversible pulpitis Between the

ages of 18 and 60

Exclusion criteria:

Being in late pregnancy or breastfeeding Having Asthma or any allergies to diclofenac sodium or ketorolac History of gastrointestinal diseases such as stomach ulcers History of Bleeding disorders Intention to perform heart bypass surgery after receiving medication

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in a simple, individual way with the help of Random.org and by the assistant. Patients were divided into three treatment groups using random numbers generated by Random.org.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher delivers painkillers and placebo in three sealed envelopes to the clinician. Study participants receive one of the medications after randomization by an assistant.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Alborz St., Alborz Dental Clinic

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

IR.UMSU.REC.1399.268

Health conditions studied

1

Description of health condition studied

pain in tooth

ICD-10 code

K04.4

ICD-10 code description

Acute apical periodontitis of pulpal origin

Primary outcomes

1

Description

Intensity of pain

Timepoint

Measurement of patient's toothache immediately before treatment and at 6, 12 and 24 hours after treatment

Method of measurement

Visual Analog Scale Pain Assessment Form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, diclofenac sodium 100 mg analgesic made by Shafa is taken as an oral tablet and a single dose before starting treatment.

Category

Treatment - Drugs

2

Description

In this group, Ketorolac 10 mg analgesic made by Iran Hormone is used as an oral tablet and a single dose before starting treatment.

Category

Treatment - Drugs

3

Description

Control group: This group receives a placebo drug made from starch powder by a pharmacist consultant as a single oral tablet before treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Alborz Dental Clinic of Urmia
Full name of responsible person
Amir Ardalan Abdollahi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Oroumia University of Medical Sciences

Proportion provided by this source
100

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

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
امیر اردلان عبدللهی
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Associate professor
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Person responsible for updating data

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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