

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 Ketorolak 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 ketorolak 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

Country

Iran (Islamic Republic of)

Phone

+98 44 3336 3600

Email address

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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 ketorolak 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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Alborz Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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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 عبداللهی

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Other areas of specialty/work

Dentistry

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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