

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Premedication efficacy of oral Ketorolac and Ketorolac/ Acetaminophen on post endodontic treatment pain

Protocol summary

Summary

Objectives: This study aimed to evaluate the efficacy premedication of two analgesics on success of intra oral injection. Design: Sixty adult volunteers who refer to Endodontic department, Tehran Islamic Azad University, will randomly divide into three groups (n=20) in this prospective randomized triple-blind clinical trial. Conduct and setting: All the patients will receive a capsule including Ketorolac, Ketorolac plus Acetaminophen or placebo 45 minutes before standard infra alveolar nerve block . Endodontic access preparation will initiate after 15 minutes of initial IANB with two negative responses to the electric pulp test. Pain after root canal treatment will be recorded using Heft Parker Visual Analog Scale(VAS). The success is considered as none or mild pain after treatment. Intervention: Ketorolac/Ketorolac plus Acetaminophen/Placebo. Main outcome measures : Pain after root canal treatment during 6,12,24 and 48 hour intervals using VAS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102916845N4**
Registration date: **2015-12-12, 1394/09/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-12, 1394/09/21

Registrant information

Name

Nahid Akhlaghi

Name of organization / entity

Tehran Dental Branch Islamic Azad University

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University Tehran

Expected recruitment start date

2015-09-11, 1394/06/20

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Premedication efficacy of oral Ketorolac and Ketorolac/ Acetaminophen on post endodontic treatment pain

Public title

Premedication efficacy of two oral analgesic on post root canal treatment pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with age ranged 18-65; without systemic diseases ; without any medicine consumption; non smoking; non pregnant; non breast feeding; with asymptomatic irreversible pulpitis (Visual Analog Scale(VAS) \leq 54); no allergies and hypersensitivity history to non-steroidal anti-inflammatory drugs and acetaminophen; need root canal treatment for a mandibular molar Exclusion criteria: patients younger than 18 and older than 65; systemic

diseases; any medicine consumption; pregnant and breast feeding; VAS more than 54; allergic history to drugs; normal pulp; no need to root canal treatment

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

patients with age ranged 18-65; without systemic diseases ; without any medicine consumption; non smoking; non pregnant; non breast feeding; with asymptomatic irreversible pulpitis (Visual Analog Scale \leq 54); no allergies and hypersensitivity history to Non-steroidal anti-inflammatory drugs and acetaminophen; need root canal treatment for a mandibular molar; with understanding, accepting and signing the consent and VAS forms. Questionnaire and consent forms are blindly placed and blocked in a sealed envelope using random table.

Secondary Ids

1

Registry name

ClinicalTrials.gov

Secondary trial Id

NCT02614118

Registration date

2015-11-23, 1394/09/02

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Tehran dental Branch

Street address

No 4,10th Neyestan, Pasdaran Ave

City

Tehran

Postal code

Approval date

2015-05-05, 1394/02/15

Ethics committee reference number

ir.iau.rec.1394.139

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

Z40-Z54

ICD-10 code description

این بیماران جهت انجام درمان ریشه دندانها بدون علایم درد مراجعه مینمایند

Primary outcomes

1

Description

Pain after root canal treatment

Timepoint

6,12,24 and 48 hour intervals

Method of measurement

Pain rate based on VAS

Secondary outcomes

empty

Intervention groups

1

Description

10 mg oral Ketorolac(Iran Hurmon Co. Tehran, Iran), single dose, 45 min. before treatment

Category

Treatment - Drugs

2

Description

10 mg oral Ketorolac plus 1000 mg oral Acetaminophen(Arya Pharmaceutical Co. Tehran, Iran), single dose, 45 min before treatment

Category

Treatment - Drugs

3

Description

Oral placebo, single dose 45 minutes before treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University Tehran Dental Branch

Full name of responsible person

Dr Nahid Mohammadzadeh Akhlaghi

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice Chancellor for research of Dental Branch, Tehran
Azad University of Medical Sciences**Full name of responsible person**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice Chancellor for research of Dental Branch, Tehran
Azad 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**

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Dental Branch, Islamic Azad University

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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