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 Ketorolak, Ketorolak 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/Ketorolak 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

Country

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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) ≤ 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 ≤ 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 befor 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
Nahid mohammadzadeh Akhlaghi
Street address
No4, 10th Neyestan, Pasdaran Ave
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice 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
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Person responsible for updating data

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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