

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of Ketorolac and Ketorolac/Acetaminophen on anesthetic efficacy of Inferior Alveolar Nerve Block in patients with asymptomatic irreversible pulpitis

Protocol summary

Summary

Sixty adult volunteers will randomly divide into three groups (n=20). All 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 during dentin, access cavity preparation and root canal instrumentation will be recorded using Visual Analog Scale. The success is considered as none or mild pain during treatment. Participants including major eligibility criteria: all patients with asymptomatic irreversible pulpitis (Heft Parker visual analogue scale \leq 54) of a mandibular molar tooth without systemic diseases; non smoking; without any medicine consumption or analgesic and sedation Intervention: Ketorolac/Ketorolac plus Acetaminophen/Placebo. Main outcome measures : Pain during dentin removal , access cavity preparation and root canal instrumentation using visual analyzing scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081116845N3**

Registration date: **2015-11-24, 1394/09/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-24, 1394/09/03

Registrant information

Name

Nahid Akhlaghi

Name of organization / entity

Tehran Dental Branch Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

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Email address

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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

Comparison of Ketorolac and Ketorolac/Acetaminophen on anesthetic efficacy of Inferior Alveolar Nerve Block in patients with asymptomatic irreversible pulpitis

Public title

Comparison of two oral analgesic pre-medication on success of intraoral anesthesia

Purpose

Treatment

Inclusion/Exclusion 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

≤ 54); no allergies and hypersensitivity history to Non-steroidal anti-inflammatory drugs and acetaminophen; need root canal treatment for a mandibular molar

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

Secondary Ids

1

Registry name

ClinicalTrials.gov

Secondary trial Id

NCT02601911

Registration date

1394-08-18, 777/01/-1309

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Tehran dental Branch

Street address

10th Neyestan, Pasdaran Ave

City

Tehran

Postal code

19468

Approval date

2015-06-01, 1394/03/11

Ethics committee reference number

ir.iau.ac.ir.1394.166

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anesthesia following the injection

Timepoint

5 minutes

Method of measurement

Electric pulp tester

Secondary outcomes

1

Description

Root Canal treatment without pain

Timepoint

15 minutes following injection

Method of measurement

Pain rate based on VAS

Intervention groups

1

Description

10 mg oral Ketorolac single dose, 45 min. before treatment

Category

Treatment - Drugs

2

Description

10 mg oral Ketorolac plus 1000 mg oral Acetaminophen single dose, 45 min before treatment

Category

Treatment - Drugs

3

Description

Oral placebo

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

10th Neyestan, Pasdaran Ave Tehran Tehran

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research ,Dental Branch Islamic Azad University

Full name of responsible person

Dr Arash Azizi

Street address

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 of Research ,Dental Branch Islamic Azad University

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

Islamic Azad University Tehran Dental Branch

Full name of responsible person

Dr Nahid Mohammadzadeh Akhlaghi

Position

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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