Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 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 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 ≤ 54) of a mandibular molar tooth without systemic diseases; non smoking; without any medicine consumption or analgesic and sedation Intervention: Ketorolac/Ketorolak 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

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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
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

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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

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10th Neyestan, Pasdaran Ave Tehran Tehran

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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

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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