Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Effect Of Premedication With Naproxen Sodium On success Rate Of inferior alveolar nerve block injection in teeth With irreversible Pulpitis

Protocol summary

Summary

The aim of this study was to evaluate the effect of pretreatment with naproxen sodium on the success of inferior alveolar nerve block for teeth with symptomatic irreversible pulpitis. 60 patients with symptomatic teeth with irreversible pulpitis were randomly assigned to double-blind and placebo controlled clinical study will be selected . the patients will include the study if had not taken any analgesics for at least 12 hours before, had first or second molar of mandible with irreversible pulpitis and normal periapical radiography appearance. Patients will exclude in below conditions: subjects under 18 years of ages, allergies to take Naproxen sodium, allergic reaction to local anesthesia, pregnant women, history of significant medical condition. The patient will receive identical capsules of 550 mg of naproxen sodium or placebo 1 hour before the injection of conventional inferior alveolar nerve block. The Pain on the basis of visual analogue scale will record before treatment and during access cavity preparation and instrumentations. All the patients will control fore 48 after procedure to assess the side effects or flare-ups will associate with the endodontics treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013101615041N1**
Registration date: **2014-10-19, 1393/07/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-10-19, 1393/07/27

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ahvaz jundishapur university of medical science

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2015-02-04, 1393/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Of Premedication With Naproxen Sodium On success Rate Of inferior alveolar nerve block injection in teeth With irreversible Pulpitis

Public title

decrees pain patient during root canal therapy with consume of analgesic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:the patient included study had not taken any analgesics for at least 12 hours before; have first or second molar of mandible with irreversible pulpitis and normal periapical radiography appearance.

Exclusive criteria:patients under 18 years; patients with allergic to naproxen sodium; patients with a history of sensitivity to local anesthetics; pregnant women; a history of significant medical problems; the people who would not have consent to participate in this research project; aspirin;oral anticoagulant medications or plicamycin taken by the patient; history of angioedema; gastrointestinal disease; peptic ulcer; renal or cardiovascular disease; if the tooth has a vital pulp during cavity preparation

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahwaz Jundishapur University Of Medical Sciences

Street address
Ahwaz/university town

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Ahwaz

Postal code
61357-15794

Approval date
2013-12-21, 1392/09/30

Ethics committee reference number
ajums.REC.1393.175

Health conditions studied

1

Description of health condition studied
Painful irreversible pulpitis

ICD-10 code
K04

ICD-10 code description
Diseases of pulp and periapical tissue

Primary outcomes

1

Description
Pain score

Timepoint
Befor treatment, During treatment

Method of measurement
VAS (visual analog scale)

Secondary outcomes

1

Description
Any side effects from taking the drug

Timepoint
48 hours after treatment

Method of measurement
Patient chief complaint

Intervention groups

1

Description
control group: placebo capsules in the control group, one hour before treatment, orally, containing starch and a small amount of lactose powder

Category
Placebo

2

Description
Intervention group: Naproxen sodium capsule,550mg,Single dose, orally, one hour before to treatment

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty Of Dentistry, Jundishapur University Of Medical Sciences

Full name of responsible person
Dr Mohammad Yazdizadeh

Street address
Ahwaz, Faculty Of Dentistry

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Ahwaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jundishapur university of Medical Science
Full name of responsible person
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University town, Jundishapur University Of Medical Science
City
Ahwaz
Grant name
Grant code / Reference number
U.93089
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jundishapur university of Medical Science
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*