

# 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

##### Name

Somaye Ghamari

##### Name of organization / entity

Jundishapur University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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

**City**

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**

Before 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

**City**

Ahwaz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Jundishapur university of Medical Science

**Full name of responsible person**

Dr Nader Saki

**Street address**

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

**Contact****Name of organization / entity**

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**Full name of responsible person**

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Assistant professor

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## 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*

