

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Oral Premedication with Novafen, Naproxen, and Ibuprofen on the Success of the Inferior Alveolar Nerve Block for Teeth with Symptomatic Irreversible Pulpitis

Protocol summary

Study aim

The effect of oral premedication with Novafen, Naproxen, and Ibuprofen on the success of inferior alveolar nerve block for teeth with acute irreversible pulpitis

Design

Clinical trial with control group, with parallel groups, triple-blind, randomized, phase 1 on 125 patients. The rand function of the Excel software is used for randomization.

Settings and conduct

Mashhad Faculty of Dentistry

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. acute pulpal pain in a mandibular molar 2. signs and symptoms indicating pulp vitality 3. Age 20 to 55 years 4. No medication 8 hours before treatment 5. No severe apical periodontitis 6. The ability to sense pain factors

Intervention groups

Group 1: premedication with one tablet of 400 mg Ibuprofen (Neda Pharmaceutical Co., Tehran, Iran) one hour before treatment Group 2: premedication with one tablet of Novafen (Alhavi Pharmaceutical Co., Tehran, Iran) one hour before treatment Group 3: premedication with one tablet of 250 mg Naproxen (ParsPharmaceutical Co., Tehran, Iran) one hour before treatment Group 4: premedication with placebo one hour before treatment Group 5: no premedication

Main outcome variables

The level of anaesthesia

General information

Reason for update

Acronym

پیش درمانی

IRCT registration information

IRCT registration number: **IRCT20200504047302N2**

Registration date: **2020-06-10, 1399/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-10, 1399/03/21**

Update count: **0**

Registration date

2020-06-10, 1399/03/21

Registrant information

Name

Hamid Jafarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9501

Email address

hamid_j365@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Oral Premedication with Novafen, Naproxen, and Ibuprofen on the Success of the Inferior Alveolar Nerve Block for Teeth with Symptomatic Irreversible Pulpitis

Public title

The Effect of Oral Premedication with Novafen, Naproxen, and Ibuprofen on the Success of the Inferior Alveolar Nerve Block for Teeth with Symptomatic Irreversible Pulpitis

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20 to 55 years acute irreversible pulpitis mandibular molar The ability of understanding the pain factors No medication in the past 8 hours

Exclusion criteria:

Severe apical periodontitis Sign or symptoms indicating pulp necrosis Systemic disease Pregnant or milking patient Allergic reactions to drugs

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **125**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization (computer creates random numbers between 0 and 5; numbers between zero and one in the first group, numbers between 1 and 2 in group 2, numbers between 2 and 3 in group 3, numbers between 3 and 4 in group 4, and numbers between 4 and 5 in group 5 Placed)

Blinding (investigator's opinion)

Triple blinded

Blinding description

Preparation of capsules by a person allocation to patient by another person treatment by another person (neither the researcher knows what capsule is giving to the patient, nor the patient knows what capsule is taking)

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah street

City

Mahhsad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2013-11-20, 1392/08/29

Ethics committee reference number

920276

Health conditions studied

1

Description of health condition studied

Pulp disease

ICD-10 code

K04.9

ICD-10 code description

Other and unspecified diseases of pulp and periapical tissues

Primary outcomes

1

Description

A Randomized Clinical Trial Comparing the Effect of Oral Premedication with Novafen, Naproxen, and Ibuprofen on the Success of the Inferior Alveolar Nerve Block for Teeth with Symptomatic Irreversible Pulpitis

Timepoint

1 HOUR AFTER DRUG CONSUMPTION

Method of measurement

Heft Parker method of pain measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: - Group 1: premedication with Ibuprofen 400 mg (Neda pharmaceutical company), 1 hour before treatment

Category

Other

2

Description

Intervention group: premedication with Novafen (Alhavi pharmaceutical company), 1 hour before treatment

Category

Other

3**Description**

Intervention group: premedication with Naproxen 250 mg (Pars pharmaceutical company, 1 hour before treatment

Category

Other

4**Description**

Control group: premedication with placebo, 1 hour before treatment

Category

Placebo

5**Description**

Control group: no premedication

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mashhad Faculty of Dentistry

Full name of responsible person

Hamid Jafarzadeh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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ramresearch@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Jafarzadeh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Hamid Jafarzadeh

Position

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Latest degree
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data can be shared after removing personal data of participants

When the data will become available and for how long

Open from 2020

To whom data/document is available

Researchers in academic centers

Under which criteria data/document could be used

Because information lacks individual information, there are no restrictions

From where data/document is obtainable

email to hamid_j365@yahoo.com

What processes are involved for a request to access data/document

simple email

Comments