

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Oral Premedication with Novafen and Ibuprofen on the Response of the Patients with Acute Irreversible Pulpitis to the Cold, Heat, Electric, and Pulse Oximetry Tests

Protocol summary

Study aim

The Effect of Oral Premedication with Novafen and Ibuprofen on the Response of the Patients with Acute Irreversible Pulpitis to the Cold, Heat, Electric, and Pulse Oximetry Tests

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 1 on 84 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: Age 20 to 55 years Acute irreversible pulpitis (spontaneous pain or severe and prolonged pain with cold or heat) Do not take the medicine for at least 8 hours before work Severe apical periodontitis Ability to understand pain criteria Low-rooted single-root permeable and single-channel without extensive decay or extensive repair Apox evolved Lack of cover or very extensive repairs Absence of clinical signs of necrosis Lack of systemic disease Exclusion criteria: The patient has an allergy to one of the drugs being tested A pregnant or lactating patient History of significant medical problems History of active gastric ulcer in the last 12 months History of bleeding problems or anticoagulants last month Pain over one tooth Take the medicine 8 hours before work Severe apical periodontitis Absence of acute irreversible pulpitis

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 placebo one hour before treatment Group 4: no premedication

Main outcome variables

cold test result; heat test result; electrical test result; pulse oximetry test result

General information

Reason for update

Acronym

پیش درمانی

IRCT registration information

IRCT registration number: **IRCT20200504047302N1**

Registration date: **2020-06-08, 1399/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-08, 1399/03/19**

Update count: **0**

Registration date

2020-06-08, 1399/03/19

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

2020-05-10, 1399/02/21

Expected recruitment end date

2020-06-10, 1399/03/21

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Oral Premedication with Novafen and Ibuprofen on the Response of the Patients with Acute Irreversible Pulpitis to the Cold, Heat, Electric, and Pulse Oximetry Tests

Public title
The Effect of Oral Premedication with Novafen and Ibuprofen on the Response of the Patients with Acute Irreversible Pulpitis to the Cold, Heat, Electric, and Pulse Oximetry Tests

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 20 to 55 years acute irreversible pulpitis single root/canal mandibular premolar The ability of understanding the pain factors Mature apex
Exclusion criteria:
 Drug consumption in past 8 hours Severe apical periodontitis Clinical sign of necrosis Systemic disease

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization (computer creates random numbers between 0 and 4; 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 and numbers between 3 and 4 in group 4 Placed)

Blinding (investigator's opinion)
Double blinded

Blinding description
Preparation of capsules by a 3rd 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

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2015-10-14, 1394/07/22

Ethics committee reference number

IR.mums.sd.REC.1394.19

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

Pre-treatment effect on cold test result; pre-treatment effect on heat test; pre-treatment effect on electrical test result; pre-treatment effect on pulse oximetry test result

Timepoint

1 HOUR AFTER DRUG CONSUMPTION

Method of measurement

test result as positive or negative

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use a 400 mg ibuprofen (Neda, Tehran, Iran) one hour before treatment

Category

Treatment - Drugs

2

Description

Intervention group: Take one novafen (Alhavi, Isfahan, Iran) one hour before treatment

Category

Treatment - Drugs

3

Description

Control group: premedication with placebo one hour before treatment

Category

Placebo

4

Description

Control group: Nopretreatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry

Full name of responsible person

Hamid Jafarzadeh

Street address

Daneshgah street

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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 Tafaghghodi

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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

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Person responsible for updating data

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Mashhad University of Medical Sciences
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is 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