

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The comparison of prophylactic prescription of Nabumetone and Ibuprofen on postoperative pain in symptomatic irreversible pulpitis

Protocol summary

Study aim

this study aimed to determine the effect of Nabumetone (500&750mg)premedication compared with ibuprofen 400 mg on pain after root canal treatment in patients with symptomatic irreversible pulpitis referring to Endodontics Department of Dental Branch, Islamic Azad University, Tehran, Iran during the year of 1396-97.

Design

Pragmatic, community based, parallel group, double blind, randomized controlled trial

Settings and conduct

This double-blind(a similar shape of medicines was prepared in intervention & placebo groups & evaluator & prescriber are different.) , randomized, and placebo controlled clinical trial was conducted on 88 eligible patients with moderate to severe pain who needed root canal treatment for molar teeth with the diagnosis of irreversible pulpitis.The dental pain level more than 54 according to HP-VAS is considered sympathetic . Patients are divided into 4 groups according to the randomized table: Ibuprofen (400 mg)is administered to the first case group, Nabumetone (750 mg) for the second group , Nabumetone(500 mg) for third group and oral placebo for control group . The patient, the person evaluating and controlling, are blind to the allocation. After about 30 minutes,anesthetizing is done.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1-symptomatic Irreversible pulpitis 2- Healthy participants without systemic disease 3-First & second molar of maxilla & mandible Exclusion criteria : 1- Systemic disease 2- Pregnancy and lactation 3- Taking analgesics in the last 12 hours 4- Allergic drugs 5- Periodontitis and periodontal ligament widening more than 1 mm 6- History of root canal therapy

Intervention groups

Intervention group 1: Nabumetone 750 mg; Intervention group 2: Nabumetone 500 mg; Intervention group 3: Ibuprofen 400 mg; Control group: Placebo (vitamin B)

Main outcome variables

pain severity

General information

Reason for update

Acronym

|||||

IRCT registration information

IRCT registration number: **IRCT20131214015782N7**

Registration date: **2018-05-07, 1397/02/17**

Registration timing: **prospective**

Last update: **2018-05-07, 1397/02/17**

Update count: **0**

Registration date

2018-05-07, 1397/02/17

Registrant information

Name

Peyman Mehrvarzfar

Name of organization / entity

Tehran Medical Science Branch, Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 21 8875 9644

Email address

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2639-04-21, 2018/02/01

Expected recruitment end date

2639-10-23, 2018/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of prophylactic prescription of Nabumetone and Ibuprofen on postoperative pain in symptomatic irreversible pulpitis

Public title

Effect of Nabumetone on pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

symptomatic irreversible pulpitis healthy participants (ASA I & ASA II) first & second molar of maxilla & mandible

Exclusion criteria:

systemic disease pregnancy and lactation taking analgesics in the last 12 hours allergic drugs periodontitis & PDL widening more than 1 mm History of RCT

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

balanced block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

double blind study: 1. researcher who prescribes drugs is blinded to the case & placebo medications due to all medications are encapsulated in identical size & shape capsules in pharmaceutical company. 2. patient is also blinded due to who does not know about the containing capsules. 3. outcome assessor is the main researcher who does not know about the prescribed medications. 4. statistician is absolutely blinded to prescription and assessment.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran Medical Science Branch, Islamic Azad University

Street address

No.4, Neyestan 10 Alley, Pasdaran Street

City

Tehran

Province

Tehran

Postal code

19858175

Approval date

2017-06-18, 1396/03/28

Ethics committee reference number

IR.IAU.DENTAL.REC.1396,4

Health conditions studied**1****Description of health condition studied**

post operative endodontic pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pain severity

Timepoint

measurement of pain severity before Intervention & 6,12,24,48 hours after finish the Intervention

Method of measurement

heft parker visual analog scale (0_170 mm)

Secondary outcomes

empty

Intervention groups**1****Description**

"Intervention group1": Nabumetone 750 mg, non steroidal anti-inflammatory drugs prescribe 30 minutes before intervention.

Category

Treatment - Drugs

2**Description**

"Intervention group": Nabumetone 500 mg non steroidal anti-inflammatory drugs prescribe 30 minutes before

intervention.

Category

Treatment - Drugs

3

Description

"Intervention group": Ibuprofen 400 mg non steroidal anti-inflammatory drugs prescribe 30 minutes before intervention.

Category

Treatment - Drugs

4

Description

"Control group": Placebo , prescribe 30 minutes before intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Dental Branch , Islamic Azad University

Full name of responsible person

Peyman Mehrvarzfar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Dental Branch, Islamic Azad University

Full name of responsible person

Arash Azizi

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a_azizi@dentaliau.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran Dental Branch, Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Peyman Mehrvarzfar

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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

There is no further 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

only some parts of data including age,gender & post operative pain intensity would be shared.

When the data will become available and for how long

6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Dental academic groups would receive the data provided that they contact with researching authorities.

From where data/document is obtainable

peyman mehrvarzfar 00989194889838

p_mehrvarzfar@dentaliau.ac.ir

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

Authorized letter from scientific organization should be sent to Tehran dental branch Islamic Azad University .Next following approval by competent authorities the data would be released during a period of 6 month.

Comments