Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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)

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+98 21 8875 9644

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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:
symptpmatic irreversible pulpitis healthy participants(ASAI &ASAII) first & second molar of maxilla & mandible
Exclusion criteria:
systemic disease pregnancy and lactation taking analgesics in the last 12 hours allergic drugs periodontitis & PDLwidening 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

Street address

No.4, Neyestan10 Alley, Pasdaran Street

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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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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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Person responsible for scientific inquiries

Contact

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Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

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Full name of responsible person
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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
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