

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effects of Tramadol, Novafen and Naproxen on post-operative pain following endodontic treatment

Protocol summary

Summary

Aim: eliminating or reducing pain following endodontic treatment is of great importance. The aim of this study is to compare the effects of Tramadol, Novafen and Naproxen on post-operative pain following instrumentation of root canals in teeth with irreversible pulpitis. Sample size: one hundred patients considering the inclusion and exclusion criteria were selected. Exclusion and inclusion criteria: 1. Patients were aged between 20-60 years with no systemic diseases and females were not pregnant, 2. No history of taking any analgesics or other drugs prior to presenting for treatment, and 3. Patients had moderate to severe pain associated with irreversible pulpitis in single-rooted premolars or anterior teeth. Intervention and outcome: The effect of Tramadol, Novafen and Naproxen on post-operative pain following instrumentation of root canals in teeth with irreversible pulpitis was evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903194006N2**

Registration date: **2010-06-09, 1389/03/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-06-09, 1389/03/19

Registrant information

Name

Payman Mehrvarzfar

Name of organization / entity

Dental Branch of Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

dr.p.mehrvarzfar@dentaliau.ir

Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2010-07-01, 1389/04/10

Expected recruitment end date

2010-08-11, 1389/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Tramadol, Novafen and Naproxen on post-operative pain following endodontic treatment

Public title

The effects of Tramadol, Novafen and Naproxen on post-operative pain following endodontic treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged between 20-60 years; Patients with moderate to severe pain associated with irreversible pulpitis in single-rooted premolars or anterior teeth. Exclusion criteria: systemic diseases; pregnancy in women; taking any analgesics or other drugs prior to presenting for treatment.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 100

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

Ethics committee of Dental School of Tehran Azad University

Street address

No. 4, 10th alley, Pasdaran Ave

City

Tehran

Postal code

Approval date

2010-06-28, 1389/04/07

Ethics committee reference number

7065

Health conditions studied

1

Description of health condition studied

Post operative endodontic pain

ICD-10 code

K08.8

ICD-10 code description

Other specified disorders of teeth and supporting structures

Primary outcomes

1

Description

post operative endodontic pain

Timepoint

before intervention, 6, 12 and 24 hours after treatment

Method of measurement

Visual analogue scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control: Placebo

Category

Placebo

2

Description

Intervention: group1: Tramadol Tab, 100mg in 6, 12 and 24 hours after root canal treatment

Category

Treatment - Drugs

3

Description

Intervention group 2: Novafen, 325 mg in 6, 12 and 24 hours after root canal treatment

Category

Treatment - Drugs

4

Description

Intervention group 3: Naproxen Tab, 500 mg in 6, 12, and 24 hours after root canal treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School of Tehran Azad University

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

No sponsors

Full name of responsible person

Peyman Mehrvarzfar

Street address

10th neyestan, Pasdran Ave

City

Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 No sponsors
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
 Endodontic Department, Dental School of Tehran
 Azad University, Tehran, Iran
Full name of responsible person
 Dr Paymen Mehrvarzfar
Position
 Assistant Professor
Other areas of specialty/work
Street address
 No. 4, 10th alley, Pasdaran Ave, Tehran, Iran
City
 Tehran
Postal code
Phone
 +98 912 104 5805
Fax
Email
 dr.p.mehrvarzfar@dentaliau.ir,
 mehrvarzfar@gmail.com
Web page address

Person responsible for scientific

inquiries

Contact
Name of organization / entity
 Endodontic department, Dental School of Tehran
 Azad University
Full name of responsible person
 Peyman Mehrvarzfar
Position
 Assistant professor
Other areas of specialty/work
Street address
 10th Neyestan, Pasdaran Ave
City
 Tehran
Postal code
Phone
 +98 912 104 5805
Fax
Email
 mehrvarzfar@gmail.com,
 dr.p.mehrvarzfar@dentaliau.ir
Web page address

Person responsible for updating data

Contact

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
Data Dictionary
 empty