Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 committe 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 quesionnaire

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 afetr 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 sponsers
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 sponsers
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