

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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  
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Assistant Professor  
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## Person responsible for scientific

## inquiries

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**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*