

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison of the effect of premedication with two drugs:oral Dextrometorphan and Ibuprofen on post root canal therapy pain in pateints with irriversible pulpitis in first mandibular molar.

#### Protocol summary

2017-04-23, 1396/02/03

#### Summary

None steroidal anti-inflammatory drugs are the most commonly used analgesics with gastrointestinal side effects. The researchers are looking for alternative drugs with fewer side effects. This study aims to determine the effect of the oral Dextromethorphan (N-methyl-D-aspartate receptor antagonist) in comparison with Ibuprofen in pain after root canal therapy. This double-blind randomized clinical trial has placebo controlled. Research will be done on healthy patients need endodontic treatment of first lower molar with irreversible pulpitis, spontaneous pain and no apical lesions. Patients are excluded with necrotic tooth or inability to complete treatment in one visit.45 patients participate in this research. Randomly, patients are given a single dose of dextromethorphan, ibuprofen, or placebo an hour before the beginning of treatment and receiving anesthesia. Then root canal treatment is completed in one visit. Pain intensity is evaluated by a questionnaire according to the visual analogue scaling method at intervals of 2, 4, 8 and 12 hours after root canal treatment. The patients are asked to mark in the questionnaire if they take analgesics, ultimately these patients will be excluded. Questionnaires are collected in the crown restoration appointment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016070228732N1**  
Registration date: **2017-04-23, 1396/02/03**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Elmira Ahmadpour

##### Name of organization / entity

Isfahan islamic azad university-khprasgan branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3531 0552

##### Email address

e.ahmadpour@khuisf.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Isfahan Islamic Azad University Khorasgan branch

#### Expected recruitment start date

2017-04-09, 1396/01/20

#### Expected recruitment end date

2017-09-11, 1396/06/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effect of premedication with two drugs:oral Dextrometorphan and Ibuprofen on post root canal therapy pain in pateints with irriversible pulpitis in first mandibular molar.

#### Public title

The effect of premedication on post root canal therpy pain

#### Purpose

Supportive

### **Inclusion/Exclusion criteria**

Inclusion criteria: Patients with systemic health; suffered from irreversible pulpitis with spontaneous pain in the lower first molar; The patient didn't get analgesics 12 hours before the treatment ; Have only one painful tooth; Tooth without radiographic radiolucency; viewing vital pulp during access cavity preparation; Possibility of completing treatment in one visit. Exclusion criteria: Patients with systemic disease; patients who took analgesics 12 hours before the treatment; Teeth with apical radiographic radiolucency ;necrotic tooth; Not possible to complete the treatment in one visit.

### **Age**

From **20 years** old to **50 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **45**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Single

### **Other design features**

Treatment is done by two Endodontics with crown down technique.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Isfahan Islamic Azad University khorasgan branch

##### **Street address**

Islamic Azad University, khorasgan, Isfahan, Iran

##### **City**

Isfahan

##### **Postal code**

#### **Approval date**

2017-03-09, 1395/12/19

#### **Ethics committee reference number**

IR.IAU.NAJAFABAD.REC.1395.13

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Toothache

#### **ICD-10 code**

G50-10

#### **ICD-10 code description**

Atypical facial pain

## **Primary outcomes**

### **1**

#### **Description**

pain after root canal therapy

#### **Timepoint**

2,4,6,8 hours after intervention.

#### **Method of measurement**

Visual Analog Scaling

## **Secondary outcomes**

### **1**

#### **Description**

#### **Timepoint**

#### **Method of measurement**

## **Intervention groups**

### **1**

#### **Description**

intervention:oral Dextrometorphan,30 mgr,single dose,1 hour before root canal therapy.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

intervention:oral Ibuprofen,600 mgr,single dose,one hour before root canal therapy.

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

control:placebo,single dose,one hour before root canal therapy.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Private clinic in Isfahan

##### **Full name of responsible person**

Dr Maryam Zare Jahromi

**Street address**

no 601, 6th floor, Faraz building, In front of Shariati clinic, Shariati street, Isfahan

**City**

Isfahan

**2**

**Recruitment center**

**Name of recruitment center**

private clinic in Isfahan

**Full name of responsible person**

Dr kamal Amini

**Street address**

no 3, Yas building, In front of Asemene haftom travel agency, Mir street, Nazar crossroads, Isfahan

**City**

Isfahan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Isfahan Islamic Azad University khorasgan branch

**Full name of responsible person**

Elmira Ahmadpour

**Street address**

Islamic Azad University, Khorasgan, Isfahan, Iran

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Isfahan Islamic Azad University khorasgan branch

**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**

Isfahan Islamic Azad University khorasgan branch

**Full name of responsible person**

Elmira Ahmadpour

**Position**

Post Graduate Student of Endodontics

**Other areas of specialty/work**

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Assistant Professor of Endodontics Department of Isfahan Azad University

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**Web page address**

**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*