

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The effect of local cooling on pain during injection, root canal therapy, and after treatment in mandibular molars with irreversible pulpitis

#### Protocol summary

##### Summary

The aim of the present study is to evaluate the effect of local cooling on pain perception during local anesthesia injection, root canal therapy and post-operative pain in mandibular molars with irreversible pulpitis. The inclusion criteria include persons without systemic diseases with minimum age of 18 years old, having first or second mandibular molar tooth diagnosed with irreversible pulpitis, normal periapical radiographic appearance, without percussion sensitivity, having no pain before treatment; and absence of taking medication within 6 hours before treatment. The exclusion criteria are: presence of sensitivity to lidocaine with 1:80,000 epinephrine, periodontal ligament widening; and pregnancy or lactation. In a randomized double-blinded clinical trial, one hundred patients will be divided into two groups of 50 patients each. In group I, patients will receive frozen gel packs for 5 minutes prior to inferior alveolar nerve block injection, while in the second group a gel pack at room temperature would be used. Patients will be asked to rate their pain using a Visual Analogue Scale immediately after the injection, during root canal therapy and at times 6, 12, 24, 36, 48, and 72 hours after treatment. Two different persons are responsible for applying the gel packs and performing root canal treatments. The practitioner who performs root canal therapy and statistic analyzer remains unaware of the groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013101214985N1**

Registration date: **2014-01-31, 1392/11/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-01-31, 1392/11/11

##### Registrant information

###### Name

Maryam Raouf

###### Name of organization / entity

Kerman University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 1211 8071

###### Email address

m\_raouf@kmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research, Kerman University of Medical Sciences

##### Expected recruitment start date

2013-11-23, 1392/09/02

##### Expected recruitment end date

2014-04-14, 1393/01/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of local cooling on pain during injection, root canal therapy, and after treatment in mandibular molars with irreversible pulpitis

##### Public title

The effect of local cooling on pain related to root canal therapy

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Persons without systemic diseases with minimum age of 18 years old; having first or second mandibular molar tooth diagnosed with irreversible pulpitis; normal periapical radiographic appearance; without percussion sensitivity; having no pain before treatment; absence of taking medication within 6 hours before treatment. Exclusion criteria: Presence of sensitivity to lidocaine with 1:80,000 epinephrine; presence of periodontal ligament widening; pregnancy or lactation.

### **Age**

From **18 years** old to **80 years** old

### **Gender**

Both

### **Phase**

N/A

### **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**

Not used

### **Assignment**

Parallel

### **Other design features**

Two different persons are responsible for applying the gel packs and performing root canal treatments. The practitioner who performs root canal therapy and statistic analyzer remain unaware of the groups.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

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

Research Ethics Committee of Kerman University of Medical Sciences

##### **Street address**

Research Vice-Chancellor Office, Ebn Sina Street, Jahad Blvd, Kerman, Iran

##### **City**

Kerman

##### **Postal code**

##### **Approval date**

2013-04-08, 1392/01/19

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

ka/92/139

## **Health conditions studied**

### **1**

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

Irreversible pulpitis of first or second mandibular molars

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

k04.0

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

بیماریهای پالپ و پری آپیکال

## **Primary outcomes**

### **1**

#### **Description**

Pain degree

#### **Timepoint**

During needle insertion

#### **Method of measurement**

Visual Analogous Scale (VAS)

### **2**

#### **Description**

Pain degree

#### **Timepoint**

During injection

#### **Method of measurement**

Visual Analogous Scale (VAS)

### **3**

#### **Description**

Pain degree

#### **Timepoint**

During treatment

#### **Method of measurement**

Visual Analogous Scale (VAS)

### **4**

#### **Description**

Pain degree

#### **Timepoint**

At times 6, 12, 24, 36, 48 and 72 hours after treatment

#### **Method of measurement**

Visual Analogous Scale (VAS)

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Inferior alveolar nerve block after cooling of the skin over the injection site

#### **Category**

Treatment - Other

## 2

### Description

Inferior alveolar nerve block without cooling of the skin over the injection site

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Dentistry, Kerman University of Medical Sciences.

##### Full name of responsible person

Siamak Samanipoor

##### Street address

Endodontic Department, School of Dentistry, Shafa Street, Jomhoori Eslami Boulevard, Kerman, Iran

##### City

Kerman

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Reza Malekpour Afshar

##### Street address

Research Vice-Chancellor Office, Ebn Sina Street, Jihad Blvd, Kerman, Iran

##### City

Kerman

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Kerman University of Medical Sciences

##### 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

Kerman University of Medical Sciences

### Full name of responsible person

Siamak Samanipoor

### Position

Resident of Endodontics

### Other areas of specialty/work

### Street address

Department of Endodontics, School of Dentistry, Shafa Street, Jomhoori Eslami Blvd, Kerman, Iran

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Maryam Raouf

#### Position

Assistant Professor

#### Other areas of specialty/work

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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*