

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, Jihad 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

City

Kerman

Postal code

Phone

+98 34 1247 7388

Fax

+98 34 1211 8073

Email

s_samanipoor@yahoo.com

Web page address

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

Street address

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

City

Kerman

Postal code

Phone

+98 34 1211 9021

Fax

+98 34 1211 8073

Email

m_raouf@kmu.ac.ir

Web page address

Person responsible for updating data

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

City

Kerman

Postal code

Phone

+98 34 1247 7388

Fax

+98 34 1211 8073

Email

s_samanipoor@yahoo.com

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