

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The effect of mucosal cooling and topical anesthesia application on pain perception during infiltration injection and latency time of anesthesia for maxillary central incisors

#### Protocol summary

##### Summary

Infiltration injections for maxillary central incisors at the labial site is considered to be one of the most painful injection sites in the mouth. Different strategies are being used to avoid the pain associated with the needle prick but none has proven to be the answer to the problem. The purpose of the present study is twofold: (a) to evaluate the effect of local cooling on the pain perceived during needle penetration and anesthetic injection of local anesthesia in patients, and (b) to assess the time elapsed between the injection and no response to pulp testing. In a crossover double-blind clinical trial, 30 dental students participate. Inclusion criteria include healthy patients with intact central incisors and the ability to understand the use of pain scales. Using any type of analgesics, sedative, or antianxiety medications during 48 h before the study and allergy to lidocaine are the exclusion criteria. Participants will be randomly allocated to receive an infiltration injection with application of topical anesthesia, precooling with refrigerant spray or without anything. Immediately after the injection of 1.8 ml of lidocaine with 1:80,000 epinephrine, the volunteers will be asked to rate their pain level during needle penetration and during anesthetic solution. The responses of the tooth to electric pulp testing will be recorded every 2 minutes till no response to the test. The dentist will be responsible for administering anesthesia the attending nurse will ask the participants to score the level of pain. The nurse and statistic analyzer remains unaware of the groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014042817477N1**  
Registration date: **2014-06-28, 1393/04/07**

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

Last update:

Update count: **0**

##### Registration date

2014-06-28, 1393/04/07

##### Registrant information

###### Name

Saeede Sadr

###### Name of organization / entity

Hormozgan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 76 1335 0256

###### Email address

saeede.sadr@hums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kerman University of Medical Sciences

##### Expected recruitment start date

2014-05-05, 1393/02/15

##### Expected recruitment end date

2014-07-19, 1393/04/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of mucosal cooling and topical anesthesia application on pain perception during infiltration injection and latency time of anesthesia for maxillary central

incisors

## Public title

Compression methods of pain relief during infiltration injection anesthesia for maxillary central incisors

## Purpose

Treatment

## Inclusion/Exclusion criteria

The inclusion criteria: healthy volunteers (ASA I) who had intact maxillary central incisors that responded to an electric pulp tester and had no tenderness to palpation and percussion and no advanced periodontal disease; ability to understand the use of pain scales; no toxic habits (including alcohol abuse, smoking or regular cannabis smoking or other drug use); absence of acute or chronic infections in the oral and maxillofacial area. The exclusion criteria: those had taken opioid, nonopioid analgesics, steroids, antidepressants or sedatives within 48 h before the study; those who were pregnant; those incapable of giving informed consent; patients with known allergies to lidocaine or to epinephrine; those with peripheral neuropathy; those reporting specific phobia related to dental settings or history of traumatic dental injury.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 30

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kerman University of Medical Sciences

##### Street address

Kerman University of Medical Sciences, Shafa Street,  
Kerman, Iran

##### City

Kerman

## Postal code

## Approval date

2013-01-31, 1391/11/12

## Ethics committee reference number

k/91/22

## Health conditions studied

### 1

#### Description of health condition studied

Pain of needle insertion and injection during buccal infiltration and latency time of anesthesia for maxillary central incisors

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain during insertion and injection local anesthesia

#### Timepoint

During insertion and injection local anesthesia

#### Method of measurement

Heft Parker Visual Analog Scale

## Secondary outcomes

### 1

#### Description

Assess the time elapsed between the injection and no response to pulp testing

#### Timepoint

Two minutes interval after anesthesia infiltration

#### Method of measurement

Respond to electric pulp tester

## Intervention groups

### 1

#### Description

Using topical anesthesia at the injection site before infiltration of local anesthetics in the buccal mucosa for 1 minute

#### Category

Treatment - Other

### 2

#### Description

Cooling the injection site before infiltration of local anesthetics in the buccal mucosa for 5 seconds

#### Category

Treatment - Other

**3**

**Description**

Without use topical anesthesia and cooling at the injection site before infiltration of local anesthetics in the buccal mucosa

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Kerman Faculty of Dentistry

**Full name of responsible person**

**Street address**

**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**

Kerman University of Medical Sciences, Shafa Street, Kerman, Iran

**City**

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**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**

Hormozgan University of Medical Sciences

**Full name of responsible person**

Saeede Sadr

**Position**

Assistant Professor

**Other areas of specialty/work**

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## **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*