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
Useing 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
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
Hormozgan University of Medical Sciences
Full name of responsible person
Saeede Sadr
Position
Assistant Professor
Other areas of specialty/work
Street address
Bandar Abbas Faculty of Dentistry, Naser Blvd, Bandar Abbas, Hormozgan, Iran
City
Bandar Abbas
Postal code
Phone
+98 76 1335 0256
Fax
Email
saeede.sadr@hums.ac.ir
Web page address

Person responsible for scientific 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
Street address
Bandar Abbas Faculty of Dentistry, Naser Blvd, Bandar Abbas, Hormozgan, Iran
City
Bandar Abbas
Postal code
Phone
+98 76 1335 0256
Fax
Email
saeede.sadr@hums.ac.ir
Web page address

Person responsible for updating data

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
Street address
Bandar Abbas Faculty of Dentistry, Naser Blvd, Bandar Abbas, Hormozgan, Iran
City
Bandar Abbas
Postal code
Phone
+98 76 1333 0256
Fax
+98 76 1335 0458
Email
sadrsaeede@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