

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The influence of Lidocaine temperature change on injection pain and analgesia success in maxillary central incisors

Protocol summary

Study aim

Determining the influence of Lidocaine temperature change on injection pain and analgesia success in maxillary central incisors

Design

A crossover double blinded randomized clinical trial on 100 volunteer, Random digit table will be used for randomization

Settings and conduct

In a crossover study injection pain and anesthesia success rate will be evaluated at the Endodontic Department of Kerman Dental School. Three different persons will be participated. The volunteers, the injector, the researcher who will be responsible for evaluating the tooth response to the electric pulp tester. In each stage, the pain during injection and the success rate of anesthesia were evaluated in two intervention groups: 1- temperature of 37 ° and intervention 2-with room temperature. Injection pain will be evaluated with visual analogue scale and anesthesia success will be evaluated with electric pulp tester.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age more than 18 years, no contraindications to injecting Lidocaine with Epinephrine, having no systemic disease, do not taking narcotic drugs or analgesic drugs in recent 48 hours before the study. Exclusion criteria: Root canal treated teeth, open apex teeth, presence of periapical lesion

Intervention groups

Intervention 1: Injection single dose of Lidocaine 2% with Epinephrine 1:80000 (Iran, Tehran, Darupakhsh) at 37 C temperature Intervention 2: Injection single dose of Lidocaine 2% with Epinephrine 1:80000 (Iran, Tehran, Darupakhsh) at room temperature

Main outcome variables

Injection pain, Anesthesia success

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090609002016N10**

Registration date: **2018-10-13, 1397/07/21**

Registration timing: **prospective**

Last update: **2018-10-13, 1397/07/21**

Update count: **0**

Registration date

2018-10-13, 1397/07/21

Registrant information

Name

Masoud Parirokh

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1245 7931

Email address

m_parirokh@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-08, 1397/08/17

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The influence of Lidocaine temperature change on injection pain and analgesia success in maxillary central incisors

Public title

Investigating the influence of temperature change of analgesia liquid on analgesia success

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 18 years No consumption of analgesic and antidepressant medications during recent 48 hours No contraindications or sensitivity for injecting lidocaine with epinephrine Having no systemic disease

Exclusion criteria:

No response to the cold test Having sensitivity to percussion Having sensitivity to palpation Previous history of root canal therapy Internal or external resorption

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

More than 1 sample in each individual

Number of samples in each individual: **2**

Due to the cross-design of the study, the maxillary central incisors teeth of each person will be tested twice in this study this means that the anesthetic solution injected once at room temperature and two weeks later at 37 ° C (or vice versa).

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the volunteers are divided into Intervention 1 or Intervention 2 groups in crosswise manner, to determine the group to which the volunteers are assigned, the table of random numbers is used to extract some numbers. Numbers 1 to 10 are written on a piece of paper and the papers are folded. Each volunteer picks a paper, the odd numbers represent intervention 1 and the even numbers represent the intervention 2.

Naturally, the second time (with a two week interval) receives a different intervention from the first series.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, three persons are kept blinded to the studied groups: 1. The injector, 2. The volunteer, 3. The person who evaluates the analgesia success after injection. Blinding process of the injector: the fourth

person has prepared analgesia liquids with different temperatures. These liquids are kept in syringes covered with paper wraps and are delivered to the injector so that he cannot understand the liquid temperatures. Blinding process of the analgesia success evaluator: the person who evaluates the analgesia is different with the injector. the evaluator is not informed of the injected analgesia temperature. The pain caused by the injection is graded with a visual analogue scale (VAS), pain score from zero (no pain) to ten (severe pain) which is reported to evaluator by volunteer. Blinding process of the volunteer: before the study, the volunteer is informed of the nature of the study, his blindness during the study, and his questions are answered. Each volunteer randomly picks a paper between 1 to 10 the odd numbers represent intervention 1 and the even numbers represent the intervention 2. The volunteers does not know the temperature of the analgesia liquid and their groups.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethic Committee of Kerman University of Medical Sciences

Street address

Vice-chancellor for Research, Building of Kerman University of Medical Sciences, Tahmaseb-abad cross, Jihad Street

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.KMU.REC.1396.2419

Health conditions studied

1

Description of health condition studied

Anesthesia injection pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain during injection

Timepoint

At the time of local anesthetic injection

Method of measurement

Using visual analogue scale (VAS)

2

Description

Success rate of anesthetic depth

Timepoint

After injection of local anesthesia

Method of measurement

Pulp tester

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Injection single dose of Lidocaine 2% with Epinephrine 1:80000 (Iran, Tehran, Darupakhsh) at 37 C temperature to 50 volunteer

Category

Treatment - Other

2

Description

Intervention group 2: Injection single dose of Lidocaine 2% with Epinephrine 1:80000 (Iran, Tehran, Darupakhsh) at room temperature to 50 volunteer

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontic Department, Kerman Dental School

Full name of responsible person

Dr. Masoud Parirokh

Street address

School of Dentistry, Shafa street

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 1245 7931

Email

masoudparirokh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhti

Street address

Vice Chancellor for Research of Kerman University of Medical Sciences, Tahmsb Abbad Cross Raod, Kerman

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 1245 7931

Email

abpardakhty@kmu.ac.ir

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Masoud Parirokh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Shafa Street

City

Kerman

Province
Kerman
Postal code
7618759689
Phone
+98 342118074
Fax
+98 34 1211 8073
Email
m_parirokh@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Masoud Parirokh
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Headquarter Building of Kerman Medical Sciences
University, Jomhori Eslami Bloubvared
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 1245 7931
Fax
+98 34 1211 8073
Email
m_parirokh@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Sina Kakooei
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Oral and Dental Research Center and Vice-Chancellor
for Research, Kerman University of Medical Sciences,
Shafa street
City
Kerman
Province
Kerman
Postal code
7618759554
Phone
+98 34 3211 3736
Email
s.kakooei@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available