Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Effect of heated local anesthetic on pain perception upon oral injection

Protocol summary

Study aim
The aim of this study is the effect of injection with temperature of 37 ° C to reduce the pain caused by maxillary infiltration and compare it with inection at 21 ° C (room temperature) in the same person.

Design
Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an calculator.

Settings and conduct
The side of the jaw of the patients who are came to the Oral and Maxillofacial surgery department of Tehran Azad Dental University will be allocated by randomization method to the case and control groups. According to a pilot study, lidocaine cartridges were brought to a temperature of 40 by a heater. After one minute, which was the time to put the carpool and needle in the syringe, the carpool temperature reached 37 ° C, which will be injected on the case side. At the control side, the carpool will be injected at room temperature. The study will be blinded. The person who is injected will not be aware of the tempreature of the injection. Immediately after injection, each person will be asked to express their pain levels from zero to one hundred, so that zero means no pain and one hundred means unbearable pain.

Participants/Inclusion and exclusion criteria
Individuals with ASA1 status whom do not have dental pain or infections in the maxillary premolar area and not taking NASIDS, benzodiazepins and antidepressants are the cases. they don't have lidocaine allergies and neuropathy

Intervention groups
Case group: side of the jaw of the patients whom are taking hot injections. Control group: side of the jaw of the patients whom are taking room temperature.

Main outcome variables
Age, sex, Infection in the injection area; Dental pain in the injection area; Lidocaine allergy; Neuropathy; NSAID use; Benzodiazepine use; Antidepressant use; Pain intensity after injection.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190222042802N1**
Registration date: **2019-06-08, 1398/03/18**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-08, 1398/03/18**
Update count: **0**

Registration date
2019-06-08, 1398/03/18

Registrant information

Name
Rayhaneh Pahlevan

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2256 4571

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drrhpn@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-11, 1397/12/20

Expected recruitment end date
2019-06-10, 1398/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of heated local anesthetic on pain perception upon oral injection

Public title
Effect of heated local anesthetic on pain perception upon oral injection

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Have American Society of Anesthesiologists 1 health status

Exclusion criteria:
Dental pain or infection at the puncture site Not use nonsteroidal anti-inflammatory drugs in one week prior to study Not use Banzodiasepines or anti-depressant drugs in the 2 months prior to the study Neuropathy in facial area Alergy to lidocaine

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
In each person 2 injections in each side of jaw

Randomization (investigator's opinion)
Randomized

Randomization description
The randomized method is a sequential or continuous referral to the Department of Dentistry's Department of Surgery. Random unit: Individual Randomization tool: The upper jaw of the referring people will be randomly assigned the RAN number calculator to select the first injection (cold or hot) on the dominant side of the referral. According to the contract, if the given number is paired, a hot injection, and if the given number is one, cold injections will be performed on the dominant side (right or left).

Blinding (investigator's opinion)
Single blinded

Blinding description
In this research, the patient will not be aware of the temperature of the carpool; however the injectable person and reasurcher will be aware of the temperature by warming up the carpools and placing them in the syringe .

Placebo
Not used

Assignment
Parallel

Other design features
Split- mouth

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Azad University of Dental Science

Street address
No.9, Neyestan Ave., Pasdaran Blvd., Azad University of Dental Science

City
Tehran

Province
Tehran

Postal code
1946853314

Approval date
2019-02-03, 1397/11/14

Ethics committee reference number
IR.IAU.DENTAL.REC.1397.039

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
intensity of pain

Timepoint
immediately after injection

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injection, on a randomly selected side, using a short needle of 30 gauges and a 0.9 ml volume of 1.8 ml carp after an aspiration at 0.15 ml / s will be administered. The bow needle to the bone and the needle needle size will be 2 mm. The injection site of Moucobacul Fold will be in the premolar area. In all injections, an Abslange will be used to remove soft tissue so that pain can not be relieved by pressure on the injection site. Lidocaine 2% cartridges containing 1:

100,000 epinephrine from the Daroo Pakhsh Company will be heated by the Tommee tippee heater of the UK at a temperature of 40 ° C. After one minute, the approximate time of insertion of the carpool and needle into the syringe is injected On the side of the case at 37 ° C (body temperature). These numbers are obtained for heating by conducting a pilot study

Category

Treatment - Surgery

2

Description

Control group: injection will be administered on contralateral side at room temperature.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehram Islamic Azad University of Dental Science

Full name of responsible person

Afshin Haragi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Ali Hassani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Study protocol, statistical analysis map, informed consent form, clinical study report, code used in the analysis and data dictionary will be shared and the personal information of the participants will not be shared.

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available
All those who have access to the article can view the data.

Under which criteria data/document could be used
Use of data is strictly for reference in other articles.

From where data/document is obtainable
go to the Islamic Azad University Faculty of dental science on 9th Neyestan, Pasdaran Ave., or the author of the article, Reyhaneh Pahlavan, on 09129619673 and drrhpn@gmail.com.

What processes are involved for a request to access data/document
The claimant should visit the site where the article was published and enter it by name and specification of the article so that it can access the original text and information.

Comments