Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Effect of prewarming and precooling of mucosal injection site on maxillary central incisor labial infiltration anesthesia pain

Protocol summary

Study aim

Determining the effect of prewarming and precooling of mucosal injection site on maxillary central incisor labial infiltration anesthesia pain

Design

It is a crossover and before-after clinical trial study in which each participant had the roles of the control group, intervention 1 and intervention 2, respectively, in 3 consecutive days using lottery.

Settings and conduct

A clinical trial study was designed in which each participant received 3 injections in 3 consecutive days on the same central maxillary tooth: the first day included a labial infiltration injection of one sided maxillary central tooth (control group), the second day as experimental group 1 received ice pack, and the third day as experimental group 2 received hot pack, each intervention in one minute. Then injection was performed using lidocaine. Comparison of pain between groups in before and after intervention was done.

Participants/Inclusion and exclusion criteria

The participants included candidates dental students. Inclusion criteria: Presence of sound maxillary central and lateral incisors, no allergy to lidocaine, absence of severe periodontal disease, no history of allergy to local anesthetic agents or sulfite, no intake of medications interfering with local anesthetic agent, and absence of fever and systemic diseases. Exclusion criteria: Unwillingness for participation in the study, history of anaphylactic shock, and pregnancy.

Intervention groups

Experimental group 1: Labial infiltration anesthesia for the maxillary central incisor with ice pack in the labial mucousa for 1 minute, and then they received lidocaine anesthesia. Experimental group 2: Labial infiltration anesthesia for the same maxillary central incisor with heat pack in labial mucousa for 1 minute , and then they received lidocaine anesthesia.

Main outcome variables

Anesthetic injection pain of labial infiltration in the central maxilla

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230313057710N3**
Registration date: **2023-08-14, 1402/05/23**
Registration timing: **retrospective**

Last update: **2023-08-14, 1402/05/23**
Update count: **0**

Registration date

2023-08-14, 1402/05/23

Registrant information

Name

Zahra Khosravani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-23, 1396/10/02

Expected recruitment end date

2018-05-30, 1397/03/09

Actual recruitment start date

2017-12-28, 1396/10/07

Actual recruitment end date

2018-05-27, 1397/03/06

Trial completion date
2018-06-24, 1397/04/03

Scientific title
Effect of prewarming and precooling of mucosal injection site on maxillary central incisor labial infiltration anesthesia pain

Public title
Effect of prewarming and precooling of mucosal injection site on maxillary central incisor labial infiltration anesthesia pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Presence of sound maxillary central and lateral incisors
Exclusion criteria:
History of anaphylactic shock Pregnancy History of trauma to maxillary central incisors History of allergy to lidocaine and sulfide Present of severe periodontal disease Intake of medications affecting pain perception (such as beta blockers and opioids) Intake of medications interacting with local anesthetic agent Present of fever, and systemic diseases

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **3**
Each person should consecutively allocated in 3 group including control groups, ice pack and cold pack, respectively.
Actual sample size reached: **20**
More than 1 sample in each individual
Actual sample size in each individual: **3**
The statistician used the random assignment by lottery for determining sequence of intervention allocation to the participants. Therefore, each person was consecutively allocated in 3 group including control groups, ice pack and cold pack, respectively. All 3 interventions were performed on the same tooth in each participant.

Randomization (investigator's opinion)
Randomized

Randomization description
In the present study, the participants in the control, intervention 1 and intervention 2 groups were the same, and selected using available sampling method. The statistician used the random assignment by lottery for determining sequence of intervention allocation to the participants. Therefore, the participants were assigned on the first day as the control group, on the second day as experimental group 1 (applying an ice pack), and on the third day as experimental group 2 (warm pack).

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding of participants was not possible due to the nature of the study. However, the statistician who analyzed the results was blinded to the group allocation of data.

Placebo
Not used

Assignment
Crossover

Other design features
A clinical trial study was designed in which each participant received 3 injections in 3 consecutive days on the same central maxillary tooth. The statistician used the random assignment by lottery for determining sequence of intervention allocation to the participants. Therefore, the participants were assigned on the first day as the control group (receiving labial infiltration injection of unilateral maxillary central tooth), on the second day as experimental group 1 (applying an ice pack), and on the third day as experimental group 2 (warm pack). Comparison of pain between groups (after intervention) and before-after was done.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethix Committee of Isfahan University of Medical Sciences
Street address
Hezar Jerib street, Isfahan University of Medical Sciences, , Isfahan, Iran
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8174673461

Approval date
2019-06-26, 1398/04/05

Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.204

Health conditions studied

1

Description of health condition studied
Maxillary central incisor labial infiltration anesthesia pain

ICD-10 code
K00-K14

ICD-10 code description
XI Diseases of the digestive system

Primary outcomes

1

Description
Maxillary central incisor labial infiltration anesthesia pain
Timepoint
During needle insertion and release of anesthetic agent
Method of measurement
The participants expressed the level of pain they experienced during needle insertion and release of anesthetic agent using a 100-mm visual analog scale (VAS), and Wong-Baker Faces pain rating scale.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: After placing an ice pack over the injection site in the labial mucosa for 1 minute, Labial infiltration anesthesia of maxillary central incisors with local anesthesia (lidocaine) was done. The ice pack was fabricated by filling the fingers of a Latex glove with water, tying it, cutting the rest of the glove, and placing it in a freezer. All ice packs were checked to ensure 0°C temperature without thawing. All injections were performed by an aspirating dental injection syringe (Novocol Ontario, Canada) with a short 27-gauge needle (Made in France). 0.6 mL of 2% lidocaine with 1:80,000 Epinephrine was injected into the labial vestibule of maxillary central incisor. The needle was inserted into the tissue by 3-5 mm, aspiration was performed, and the anesthetic agent was released. Upon completion of injection, the participants expressed the level of pain they experienced during needle insertion and release of anesthetic agent using a 100-mm visual analog scale (VAS) , and Wong-Baker Faces pain rating scale (WBFPRS).
Category
Treatment - Devices

2

Description
Intervention group2: After placing an heat pack over the injection site in the labial mucosa for 1 minute, Labial infiltration anesthesia of maxillary central incisors with local anesthesia (lidocaine) was done. The heat pack was fabricated by filling a Latex glove with water, tying it, and heating it in a water bath at 50°C (Figure 1). The water temperature was measured after removal from the water bath and prior to placement over the mucosa. To obtain optimal results, a minimum temperature rise of 3-4°C of the mucosa was required. All injections were performed by an aspirating dental injection syringe (Novocol Ontario, Canada) with a short 27-gauge needle (Made in France). 0.6 mL of 2% lidocaine with 1:80,000 Epinephrine was injected into the labial vestibule of maxillary central incisor. The needle was inserted into the tissue by 3-5 mm, aspiration was performed, and the anesthetic agent was released. Upon completion of injection, the participants expressed the level of pain they experienced during needle insertion and release of anesthetic agent using a 100-mm visual analog scale (VAS) , and Wong-Baker Faces pain rating scale (WBFPRS).
Category
Treatment - Devices

3

Description
Control group: Labial infiltration anesthesia of maxillary central incisors was performed with lidocaine without the intervention of cold or heat packs. All injections were performed by an aspirating dental injection syringe (Novocol Ontario, Canada) with a short 27-gauge needle (Made in France). 0.6 mL of 2% lidocaine with 1:80,000 Epinephrine was injected into the labial vestibule of maxillary central incisor. The needle was inserted into the tissue by 3-5 mm, aspiration was performed, and the anesthetic agent was released. Upon completion of injection, the participants expressed the level of pain they experienced during needle insertion and release of anesthetic agent using a 100-mm visual analog scale (VAS) , and Wong-Baker Faces pain rating scale (WBFPRS).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
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Full name of responsible person
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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Zahra Khosravani

Position
Student in endodontics

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

Not applicable

Data Dictionary

Not applicable