

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of using local anesthesia gel on the amount of pain during dental anesthesia injection

Protocol summary

Study aim

The effect of using local anesthetic gel on the amount of pain during the injection of dental local anesthesia

Design

The clinical trial containing control group, with parallel groups, single-blinded (patient), randomized by SPSS statistical software into blocks of 6, the expected sample size is 30 people (each person has two samples) and therefore the total sample size It is 60.

Settings and conduct

Surgery department of Semnan Faculty of Dentistry's patients will be included in the study if eligible. SPSS statistical software randomly selects the side of the jaw that the local anesthetic is applied first in each patient. Therefore, the side of the control and intervention groups is determined. In this single-blind study, due to the use of a placebo, the patient will not know the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent to participate in this study, Patients without systemic disease, Patients without epinephrine, lidocaine and benzocaine allergy, Patients who need tooth extraction and there is a tooth corresponding to the intervention tooth on the opposite side of the jaw arch as a reference tooth. Exclusion criteria: Pregnant or Lactating patients, Patients who have taken systemic painkillers 4-6 hours before surgery, with localized abscess

Intervention groups

Intervention group: injection of local anesthesia along with the use of local anesthetic gel. Control group: injection of local anesthesia using placebo. Local anesthetic gel containing 20% lidocaine from Prodox brand will be used, and then injection of 2% Xylophen anesthetic containing 20 mg lidocaine and 12.5 mg epinephrine. Vaseline petroleum jelly is used as a placebo. The interval between 2 intervention and control sessions will be 2 weeks.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221018056224N1**

Registration date: **2023-05-25, 1402/03/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-25, 1402/03/04**

Update count: **0**

Registration date

2023-05-25, 1402/03/04

Registrant information

Name

ramin ganjkanloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 756 7586

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raminganjkanloo1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	the use or non-use of local anesthetic gel.
Scientific title	Placebo
The effect of using local anesthesia gel on the amount of pain during dental anesthesia injection	Used
Public title	Assignment
The effect of using local anesthetic gel on the amount of anesthetic injection pain	Parallel
Purpose	Other design features
Prevention	
Inclusion/Exclusion criteria	Secondary Ids
Inclusion criteria:	empty
Full consent to participate in this study Patients without systemic disease Patients without epinephrine, lidocaine and benzocaine allergy Patients who need tooth extraction and there is a tooth corresponding to the intervention tooth on the opposite side of the jaw arch as a reference tooth	Ethics committees
Exclusion criteria:	1
Pregnant patients Lactating patients Patients who have taken systemic painkillers 4-6 hours before surgery Patients with localized abscess	Ethics committee
Age	Name of ethics committee
No age limit	Ethics Committee of Semnan University of Medical Sciences
Gender	Street address
Both	Semnan University of Medical Sciences and Health Services Headquarters., Basij Blvd.
Phase	City
3	Semnan
Groups that have been masked	Province
• Participant	Semnan
	Postal code
	3514799442
	Approval date
	2022-10-10, 1401/07/18
	Ethics committee reference number
	IR.SEMUMS.REC.1401.185
Sample size	Health conditions studied
Target sample size: 30	1
More than 1 sample in each individual	Description of health condition studied
Number of samples in each individual: 2	Pain during local anesthetic injection
In each patient who enters the study, one side is considered as the control group, and the contralateral side is considered as the intervention group.	ICD-10 code
Randomization (investigator's opinion)	G89
Randomized	ICD-10 code description
Randomization description	Pain, not elsewhere classified
Patients are divided into two groups using blocks of six prepared by SPSS statistical software: in the first group, the first injection of anesthesia is performed on the right side of the jaw, and in the second group, the first injection of anesthesia is performed on the left side of the jaw. All injections will be performed by a maxillofacial surgeon in a room with an assistant. The use or non-use of anesthetic gel in the first injection will be randomly selected.	Primary outcomes
Blinding (investigator's opinion)	1
Single blinded	Description
Blinding description	Pain during local anesthetic injection
First, SPSS statistical software randomly selects which side of the jaw of the local anesthetic is applied first in each patient. Therefore, it is determined which side is selected as the control group and which side is the case group, and the anesthetic gel is applied. Based on the injection site, we define two areas and place the desired anesthesia at that point. Due to the fact that a placebo is used in the control group, the patient will be blinded to	Timepoint
	Immediately after the injection of anesthesia in each session, we ask the patient to express the amount of pain felt based on the Visual Analogue Scale chart, from one to ten. The interval between the first and second session is 2 weeks.
	Method of measurement
	Visual Analogue Scale
	Secondary outcomes
	empty

Intervention groups

raminganjkanloo1@gmail.com

1

Description

Intervention group: injection of local anesthesia along with the use of local anesthetic gel. First, SPSS statistical software randomly selects which side of the jaw of the local anesthetic is applied first in each patient. Therefore, it is determined which side is selected as the control group and which side is the case group, and the anesthetic gel is applied. As a result, in the intervention group, after placing the local anesthetic gel, anesthesia injection is performed. Local anesthetic gel containing 20% lidocaine from Prodox brand and then injection of 2% Xylophen anesthetic containing 20 mg lidocaine and 12.5 mg epinephrine. The interval between 2 intervention and control sessions will be 2 weeks.

Category

Treatment - Drugs

2

Description

Control group: injection of local anesthesia using placebo. First, SPSS statistical software randomly selects which side of the jaw of the local anesthetic is applied first in each patient. Therefore, it is determined which side is selected as the control group and which side is the case group, and the anesthetic gel is applied. As a result, in the control group, anesthesia injection is performed after placing the placebo substance. Vaseline petroleum jelly is used as a placebo, and then the injection of 2% xylophen anesthetic containing 20 mg of lidocaine and 12.5 mg of epinephrine is performed. The interval between 2 intervention and control sessions will be 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Semnan University of Medical Sciences

Full name of responsible person

Ramin Ganjkanloo

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Faculty of Dentistry., Semnan University of Medical Sciences., 17 shahrivar blvd., Semnan.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Majid Mirmohammadkhani

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Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan.

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Seyed Vahid Dehnad

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Seyed Vahid Dehnad

Position
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Latest degree
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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 not more 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

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