

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of mucosal patch and gel containing benzocaine for mucosal anesthesia during needle insertion

Protocol summary

Study aim

Determining the success rate of superficial benzocaine-containing patch anesthesia during needle insertion

Design

Clinical trial with control group, with parallel groups, randomized, on 35 patients. www.randomizer.org is used for block randomization.

Settings and conduct

Candidates are selected from the patients of Mashhad Dental School in the orthodontics department who need to extract two premolar teeth on both sides of the upper jaw. First, the mucus is cleaned and dried. The patch or gel is placed on the right mucosa (both buccal vestibule and palate). The patch remains in place for 10 minutes and the gel for 30 seconds (according to McDonald's suggested time). Then, with a 27-gauge needle and 2% lidocaine together with 100,000 epinephrine, injection is performed. Then the pain level is measured with NRS-11 (Numeric Rating Scale-11) SEM (Sounds, Eyes, Motor scale) indicators. After 10 minutes, the left side is numbed by another method (according to the numbness of the right side) and the previous step is repeated. Pain evaluation is done with the above indicators for the second stage of injection and the patient's preference is asked for each of the methods. Also, the patient's anxiety level is measured with the Beck index.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidates for similar types of injections in opposing sides of maxilla. Exclusion criteria: Mentally retarded patients, patients with systemic diseases, neither patient nor their family willing to participate in the study, uncooperative patients

Intervention groups

In the intervention group, benzocaine patch is used to reduce the pain of patients during anesthesia injection. In the control group, benzocaine gel is used to reduce the pain of patients during injection.

Main outcome variables

Amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230125057218N1**

Registration date: **2023-10-10, 1402/07/18**

Registration timing: **prospective**

Last update: **2023-10-10, 1402/07/18**

Update count: **0**

Registration date

2023-10-10, 1402/07/18

Registrant information

Name

Rasoul Sahebalam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9501

Email address

sahebalamr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-17, 1402/08/26

Expected recruitment end date

2024-03-16, 1402/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of mucosal patch and gel containing benzocaine for mucosal anesthesia during needle insertion

Public title

Comparison of anesthetic adhesive with anesthetic gel during intraoral injection

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who required two similar injection in the upper jaw bilaterally The two injections should be given within a short period of time.

Exclusion criteria:

Mentally retarded patients Patients with systemic disease Dissatisfaction of parents or the patient himself Non-cooperative patients

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **35**

More than 1 sample in each individual

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

-

Randomization (investigator's opinion)

Randomized

Randomization description

In this study permuted block technique randomizes patients between groups within a set of study participants, called a block. In this study, if any patient receives one of the treatments of gel (A) or patch (B) in the first intervention, he must receive the other treatment in the second intervention. Therefore, random allocation will be done only for 36 people. For this purpose, random allocation sequence of people will be used using Random Allocation Software and block size of four. So there will be 9 blocks of 4, then the list of blocks will be written and numbers will be assigned to them (AABB(1)- ABAB(2)-ABBA(3)-BBAA(4)- BABA(5)- BAAB(6)) Then a number is selected between 1 and 9 (for example, 1, 4, 8, etc.) Allocation of all samples will continue.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences,Dental Faculty

Street address

Vakil Abad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2023-04-16, 1402/01/27

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1402.003

Health conditions studied**1****Description of health condition studied**

Amount of pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Amount of pain

Timepoint

Immediately after injection

Method of measurement

SEM pain assessment index(Sounds, Eyes, Motor scale)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Benzocaine patch is used to reduce the pain of patients during anesthesia injection. In this study, In this study a patch that adheres to the mucous membrane containing benzocaine, a product of Merc KGaA Germany, is used, which is pasted for 10 minutes in the target area before injection with a slight pressure of the finger, and not only numbs the mucous membrane, but also leaves a color that Defines the area of the anesthetized mucosa.

Category

Other

2

Description

Control group: Benzocaine gel is used to reduce the pain of patients during anesthesia injection.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Surgery, Mashhad Faculty of Dentistry

Full name of responsible person

Rasoul Sahebalam

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Faculty of Dentistry, Vakil Abad Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah Str., next to Hoizeh Cinema, Qurashi Building, Research and Technology Vice-Chancel

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vcresraech@mums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Rasoul Sahebalam

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

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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

The details of the participants, such as age, sex, and the teeth studied, will be published by hiding the identity of the people.

When the data will become available and for how long

Access to information will be from 2025 onwards.

To whom data/document is available

Researchers working in academic and scientific institutions who need this information can have access .

Under which criteria data/document could be used

It is not prohibited to mention the source.

From where data/document is obtainable

They can refer to Mashhad Faculty of Dentistry library or Mashhad University of Medical Sciences library website.

What processes are involved for a request to access data/document

Information will be available in thesis format.

Comments