Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 51 3882 9501

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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
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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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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

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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