Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparative study of the effect of three mucous adhesives containing lidocaine, zinc acetate and tannic acid on gag reflex in dental patients

Protocol summary

Study aim

Comparing the effect of three mucous adhesives containing lidocaine, zinc acetate and tannic acid on gag reflex in dental patients

Design

The study is conducted as a controlled, randomized, double-blind clinical trial with a one-to-one descriptive ratio.the sampling is easy non-probability way. the samples will be assigned to 4 groups under study using the block random division method. A total of 228 samples will be included in this study.

Settings and conduct

The location of the project is in the radiology department of Kermanshah Faculty of Dentistry. There are 4 groups in this study. Each group contains 57 samples. In the first stage, people's gag reflex is measured using radiographic films. After 5 minutes of the first stage, 2 grams of mucous adhesives are placed in the distal teeth 7 and 8 in the soft and hard palate of the intervention groups for 10 to 15 minutes, then the gag reflex is evaluated again. This work is done by a doctor who, firstly, is unaware of the research hypothesis, and secondly, he is not aware of how people are assigned to intervention groups. Blind people in this study are researchers, participants and outcome assessors.

Participants/Inclusion and exclusion criteria

inclusion criteria : having a gag reflex when placing the radiology film in the mouth: Being over 18 years old and It is also having consent to enter the research. non-entry criteria: patients who had any central and peripheral nerve lesions, oral lesions, and a history of substance abuse.

Intervention groups

In this study, there are 4 groups, each group is assigned a type of mucous adhesive. Intervention groups include: 1) Placebo 2) Mucosal adhesive containing 2% lidocaine 3) Mucosal adhesive containing 2% tannic acid 4) Mucosal adhesive containing 2% zinc acetate

Main outcome variables

The main result is the effect of the intervention on the gag reflex.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220211053997N1**
Registration date: **2022-12-19, 1401/09/28**
Registration timing: **prospective**

Last update: **2022-12-19, 1401/09/28**
Update count: **0**

Registration date

2022-12-19, 1401/09/28

Registrant information

Name

Hosna Seyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative study of the effect of three mucous adhesives containing lidocaine, zinc acetate and tannic acid on gag reflex in dental patients

Public title
Effect of lidocaine, zinc acetate and tannic acid on gag reflex

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Having a gag reflex when placing the radiology film in the mouth Be over 18 years old Having consent to enter the research

Exclusion criteria:
Patients who have any central and peripheral nerve damage Patients with any oral lesions Patients with a history of substance abuse

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **228**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, given that we want the number of samples assigned to four groups to be the same at any time, the block random division method is used. For this purpose, first all four combinations are written, which includes 24 modes. Then, considering that the sample size in each group is 57, 57 times from this combination of four are selected by replacing the sample. For this, the binary sequence in the random number table is used. Binary combinations that are outside the range 01 to 24 are not considered.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study is conducted in a double-blind manner with a one-to-one allocation ratio. Blind people in this study are researchers, participants and outcome assessors. The study is conducted by a doctor (outcome assessor) who is firstly unaware of the research hypothesis and secondly is not aware of how people are assigned to intervention groups and the type of mucosal adhesive. The patient (participant) is also unaware of the research hypothesis and the type of mucosal adhesive, due to the same shape and color of the adhesives. The patient enters the study with his consent, but nothing is told to the patient regarding the decreasing or increasing effect of adhesives on the gag reflex. Also, the patient is unaware of the type of adhesive that is used for him.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
2nd floor, Hoor Building, 236 Alley, Pamchal Ave, Pardis Town

City
Kermanshah

Province
Kermanshah

Postal code
6717837134

Approval date
2022-12-11, 1401/09/20

Ethics committee reference number
IR.KUMS.REC.1401.384

Health conditions studied

1

Description of health condition studied
Gag reflex

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The degree of gag reflex of all participant samples is based on a self-reported scale by placing intraoral radiology film in their mouths.

Timepoint
In the first step, the degree of gag reflex of all samples is recorded.5 minutes after the first stage, in the second stage, after 5-10 minutes of adhesive intervention, the gag reflex is measured using the same scale.

Method of measurement
How to score the intensity of the gag reflex by the patient and with the help of a visual analog scale (absence of gag reflex, zero, very weak gag reflex, number 1, weak gag reflex, number 2, moderate gag

reflex, number 3, severe gag reflex, number 4, and the most severe reflex, number 5) is done.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: The receiving group of mucous adhesive containing 2% lidocaine. There are 57 samples in this group. Hydroxypropyl Methyl Cellulose (HPMC), Polyvinyl chloride (PVC) and Hydroxyethyl cellulose (HEC) polymers are used as the base of the mucous adhesive to make adhesives. Then 2% active ingredients are added to the base of mucous adhesives. The dosage is 2gram per use. It is used once for each sample.Placebo is placed in the form of oral adhesive by means of a swap in the distal teeth 7 and 8 on the upper right or left on the soft and hard palate for 5-10 minutes and then the gag reflex is measured.The polymers used are made by germany's merck company.These adhesive gels are checked in terms of basic specifications. The physicochemical characteristics of the adhesive gels are checked. The microbial control test is performed on the adhesive gels. The viscosity and Ph tests are performed on the adhesive gels. These adhesives do not have any harm to patients. All the materials and bases used in these adhesive mucus formulations are approved by the Food and Drug Administration (FDA) and are of a pharmaceutical grade that is not toxic to humans. Reference: American Pharmacopoeia (USP)

Category

Prevention

2

Description

Intervention group2: The receiving group of mucous adhesive containing zinc acetate 2%. There are 57 samples in this group. Hydroxypropyl Methyl Cellulose (HPMC), Polyvinyl chloride (PVC) and Hydroxyethyl cellulose (HEC) polymers are used as the base of the mucous adhesive to make adhesives. Then 2% active ingredients are added to the base of mucous adhesives. The dosage is 2gram per use. It is used once for each sample.Placebo is placed in the form of oral adhesive by means of a swap in the distal teeth 7 and 8 on the upper right or left on the soft and hard palate for 5-10 minutes and then the gag reflex is measured.The polymers used are made by germany's merck company.These adhesive gels are checked in terms of basic specifications. The physicochemical characteristics of the adhesive gels are checked. The microbial control test is performed on the adhesive gels. The viscosity and Ph tests are performed on the adhesive gels. These adhesives do not have any harm to patients. All the materials and bases used in these adhesive mucus formulations are approved by the Food and Drug Administration (FDA) and are of a pharmaceutical grade that is not toxic to humans. Reference: American Pharmacopoeia (USP)

Category

Prevention

3

Description

Intervention group3: The receiving group of mucous adhesive containing 2% tannic acid. There are 57 samples in this group. Hydroxypropyl Methyl Cellulose (HPMC), Polyvinyl chloride (PVC) and Hydroxyethyl cellulose (HEC) polymers are used as the base of the mucous adhesive to make adhesives. Then 2% active ingredients are added to the base of mucous adhesives. The dosage is 2gram per use. It is used once for each sample.Placebo is placed in the form of oral adhesive by means of a swap in the distal teeth 7 and 8 on the upper right or left on the soft and hard palate for 5-10 minutes and then the gag reflex is measured.The polymers used are made by germany's merck company.These adhesive gels are checked in terms of basic specifications. The physicochemical characteristics of the adhesive gels are checked. The microbial control test is performed on the adhesive gels. The viscosity and Ph tests are performed on the adhesive gels. These adhesives do not have any harm to patients. All the materials and bases used in these adhesive mucus formulations are approved by the Food and Drug Administration (FDA) and are of a pharmaceutical grade that is not toxic to humans. Reference: American Pharmacopoeia (USP)

Category

Prevention

4

Description

Control group: People receive placebo. 57 samples participate in this group. Hydroxypropyl Methyl Cellulose (HPMC), Polyvinyl chloride (PVC) and Hydroxyethyl cellulose (HEC) polymers are used as the base of the mucous adhesive to make adhesives. The dosage is 2gram per use. It is used once for each sample.Placebo is placed in the form of oral adhesive by means of a swap in the distal teeth 7 and 8 on the upper right or left on the soft and hard palate for 5-10 minutes and then the gag reflex is measured.The polymers used are made by germany's merck company. These adhesive gels are checked in terms of basic specifications. The physicochemical characteristics of the adhesive gels are checked. The microbial control test is performed on the adhesive gels. The viscosity and Ph tests are performed on the adhesive gels. These adhesives do not have any harm to patients. All the materials and bases used in these adhesive mucus formulations are approved by the Food and Drug Administration (FDA), and are of a pharmaceutical grade that is not toxic to humans. Reference: American Pharmacopoeia (USP)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Kermanshah Faculty of Dentistry

Full name of responsible person
Amin Golshah

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Faculty of Dentistry, in front of the post office, above Shora St., Dr. Shariati St.

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amin.golshah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Hamidreza Mozaffari

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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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Hosna Seyedi

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Position
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Other areas of specialty/work
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Person responsible for updating data

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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
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