

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)

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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

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Province

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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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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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Full name of responsible person

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Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

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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