

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the Effect of Benzydamine on the Severity of Gag Reflex

Protocol summary

Study aim

Evaluating the effect of benzydamine hydrochloride mouthwash on the rate of nausea reflex in comparison with the use of lidocaine spray in students of the School of Dentistry, Islamic Azad University in 2019

Design

Clinical trial with case and control group, with parallel groups, double-blind, randomized, phase 2 on 48 patients. This is a single-blind randomized controlled trial for patients. Subjects recruited were randomly assigned into two groups.

Settings and conduct

Among the eligible samples, 30 randomly entered the study. Before each test, no information is given about the material and the method of operation. Tests will be conducted by a trained intern under the supervision of an oral disease specialist, who must be blind to medications. Individuals who show a GTPI rating above 2 after stimulating the Landmark markings shown in Table 1 will be included in the study and then randomly assigned to the case group (benzydamine) or to the control group (lidocaine spray). In the benzydamine group, 15ml of benzydamine hydrochloride mouthwash produced by Behvazan Daroo Company, are gargled for 1 minute, then removed and re-tested after 10 minutes. 4 puffs of 50% lidocaine spray, produced by Iran Daroo Company, are used and after 5 minutes, this test will be performed again. All tests are performed on the students of the Faculty of Dentistry of the Islamic Azad University of Tehran.

Participants/Inclusion and exclusion criteria

Entry requirements: People whose nausea is higher than 2 using the GTPI standard, Had breakfast two hours before the test
Conditions for non-entry: Presence of any systemic diseases, drug allergy (Benzydamine or lidocaine), Pregnant and lactating women

Intervention groups

Case group (15ml of benzydamine hydrochloride) and
Control group (lidocaine spray 5%)

Main outcome variables

Application of benzydamine hydrochloride mouthwash reduces nausea reflexes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190608043843N2**

Registration date: **2020-06-30, 1399/04/10**

Registration timing: **prospective**

Last update: **2020-06-30, 1399/04/10**

Update count: **0**

Registration date

2020-06-30, 1399/04/10

Registrant information

Name

simin lesan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

s_lesan@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Benzydamine on the Severity of Gag Reflex

Public title

Evaluation of the Effect of Benzydamine on the Severity of Gag Reflex

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

People whose nausea rate is higher than 2 using the GTPI Standard Had breakfast two hours before the test

Exclusion criteria:

Having systemic diseases History of previous allergy to benzydamine or lidocaine Pregnancy and lactation

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

This is a single-blind randomized controlled trial for patients. Subjects recruited were consecutively and randomly assigned into two groups. The first group received benzydamine prior to procedure or whereas the second group received lidocaine.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participator: Befor each test, no information is given about the material and method of work to the patient to reduce the psychological and inductive effects as much as possible in this study. Clinical care: All tests will be performed by a trained intern under the supervision of an oral disease specialist, who must be blind to medications.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Islamic Azad University of Tehran
Dental Branch

Street address

No. 4, 9th Neyestan St., Pasdaran Ave.

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2020-06-15, 1399/03/26

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.069

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

Gag Reflex

ICD-10 code

R00-R99

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

Primary outcomes**1****Description**

Reduction of Gag reflex

Timepoint

In the Benzydamine group before the intervention and 10 minutes after the intervention in the lidocaine group before the intervention and 5 minutes after the intervention, the nausea reflex is examined.

Method of measurement

Gag Trigger Point Index (GTPI)

Secondary outcomes

empty

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

Case group: Benzydamine hydrochloride mouthwash. In the benzydamine group, 15ml of benzydamine hydrochloride mouthwash produced by Behvazan Daroo Company is gargled for 1 minute, then removed and re-tested after 10 minutes.

Category

Prevention

2**Description**

Control group: Use lidocaine spray. In the lidocaine

group, on the mucosa of the desired areas, 4 puffs of 50% lidocaine spray produced by Iran Daroo Company are used, and after 5 minutes, the test will be performed again.

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Dental Unit of Islamic Azad University of Tehran

Full name of responsible person

Simin Lesan

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No. 4, 9th Neyestan St., Pasdaran Ave.

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siminlesan@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Islamic Azad University

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Simin Lesan

Position

Assistant professor of Islamic Azad University, Dental branch of Tehran

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Islamic Azad University

Full name of responsible person

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Position

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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