

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Investigation of the Effect of Local Amitriptyline on the Severity of Gag Reflex

Protocol summary

Topical application of amitriptyline reduces nausea reflexes

Study aim

Determining the effect of amitriptyline solution in distilled water 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. Simple randomization was used to randomize

Settings and conduct

Among the eligible samples, 48 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 (amitriptyline) or to the control group (lidocaine spray). In the amitriptyline group, 75 mg of amitriptyline tablets produced by Pars Daroo Company, which is dissolved in 5 ml of distilled water, are gargled for 1 minute, then removed and re-tested after 6 minutes. 4 puffs of 50% lidocaine spray spray, produced by Iran Daroo Company, are used and after 5 minutes, the test is performed again. All tests are performed on the students of the Faculty of Dentistry of the Islamic Azad University of Tehran and in the same facult.

Participants/Inclusion and exclusion criteria

Entry requirements: People whose nausea is higher than 2 using the GTPI standard - Breakfast two hours before the test
Conditions for non-entry: systemic diseases - drug allergy (amitriptyline or lidocaine) - Pregnant and lactating women

Intervention groups

Case group (75 mg of amitriptyline dissolved in 5 ml of distilled water) Control group (lidocaine spray 5%)

Main outcome variables

General information

Reason for update

Acronym

Amitriptyline, Gag Reflex

IRCT registration information

IRCT registration number: **IRCT20190608043843N1**

Registration date: **2020-06-18, 1399/03/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-18, 1399/03/29**

Update count: **0**

Registration date

2020-06-18, 1399/03/29

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

2020-06-04, 1399/03/15

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of the Effect of Local Amitriptyline on the Severity of Gag Reflex

Public title
Investigation of the Effect of Local Amitriptyline 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 Eat Breakfast Two Hours before the Test
Exclusion criteria:
Existence of Systemic Diseases Drug
Allergy(Amitriptyline or lidocaine) Pregnant and Lactating Women

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Randomization: Among the Eligible Sample, Individuals are Randomly Assigned to the Study in this Way, each Person Falls into the Group of Amitriptyline or Lidocaine

Blinding (investigator's opinion)
Double blinded

Blinding description
Participator: Befor each Test, no Information is given about the Material and the Method of Work to the Patient to Reduce the Psychological and Inductive Effects as much as Possible in this Study. Clinical care: All Test 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

Number 4 Pasdaran Ave.Tehran, Iran,

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2020-01-11, 1398/10/21

Ethics committee reference number

IR.IAU.DENTAL.REC.1398.058

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 amitriptyline group before the intervention and 30 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: Amitriptyline tablets dissolved in distilled water _ In the amitriptyline group, 75 ml of amitriptyline tablets produced by Pars Daroo Company, which is dissolved in 5 ml of distilled water, is gargled for 1 minute, then removed and re-tested after 5 minutes.

Category

Prevention

2

Description

Witness 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 is 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

Farnaz Haji Fattahi

Street address

Number 4 Neyestan Alley 9 Pasdaran Street Tehran
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1946853314

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Email

dr_h_fattahi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farnaz Haji Fattahi

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Number 4 Neyestan Alley 9 Pasdaran Street Tehran
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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

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

Farnaz Haji Fattahi

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

Farnaz Haji Fattahi

Position

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branch of Tehran

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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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