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

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
Topical application of amitriptyline reduces nausea reflexes

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 Iran
City
Tehran
Province
Tehran
Postal code
1946853314
Phone
+98 21 2256 4571
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
Street address
Number 4 Neyestan Alley 9 Pasdaran Street Tehran Iran
City
Tehran
Province
Tehran
Postal code
1946853314
Phone
+98 21 2256 4571
Email
dr_h_fattahi@yahoo.com
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
Street address
Number 4 Neyestan Alley 9 Pasdaran Street Tehran Iran
City
Tehran
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Postal code
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Phone
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Email
dr_h_fattahi@yahoo.com

Person responsible for scientific 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
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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

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Farnaz Haji Fattahi

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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