

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of different methods of using anesthetics during impression making on the gag reflex in edentulous patients

Protocol summary

Summary

The aim of this clinical trial study is evaluation of the effect of different methods of using anesthetics during impression making on the gag reflex in edentulous patients. Nausea is a defense mechanism in front is pharyngeal and throat stimulations and all dentists and a lot of dental students had this experience with patients who have a gag reflex. Many of the dentistry acts such as preparation of oral-radiography, impression, pharyngeal and throat examination and process of operative treatment close to posterior teeth cause stimulation of nausea. In this study 35 patients referred to the Prosthodontics Department of Dentistry Faculty with severe gag reflex symptoms in initial examination will selected and then will made impression. In first step when we preparing the alginate for impressions, lidocaine anesthetic will be added to mixture of alginate and water, and then will made impression of the patient's upper jaw according to the standard procedure. In another method before the impressions, the posterior areas of the patient's palate will be stained by gel-benzocaine anesthesia and after 3 minutes impression will be made. In the other method, the standard method of upper jaw impressions of the patient will be done. In all stages, a person who don't have knowledge about study, will evaluate the items in the checklist and will note the intensity of the gag in each group. The collected data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062822947N1**

Registration date: **2015-08-30, 1394/06/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-30, 1394/06/08

Registrant information

Name

Vahid Fakhrazadeh

Name of organization / entity

Faculty of Dentistry, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3440 9387

Email address

fakhrazadeh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-08-06, 1394/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of different methods of using anesthetics during impression making on the gag reflex in edentulous patients

Public title

Evaluation of the effect of using anesthetics during impression making on the gag reflex

Purpose

Health service research

Inclusion/Exclusion criteria
Inclusion criteria: willingness to participate in the study; signing the study informed consent; having severe gagging reflex according GSI(Gagging Severity Index).
Exclusion criteria: being treated for other diseases and drug use; having the central or peripheral nervous lesions and oral lesions.

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **35**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht

City

Tabriz

Postal code

Approval date

2015-06-28, 1394/04/07

Ethics committee reference number

tbzmed.rec.1394.300

Health conditions studied

1

Description of health condition studied

Gag reflex

ICD-10 code

J39.2

ICD-10 code description

Reflex- hyperactive gag

Primary outcomes

1

Description

Gag reflex

Timepoint

Immediately after trail

Method of measurement

Gagging Severity Index

Secondary outcomes

empty

Intervention groups

1

Description

lidocaine anesthetic will be added to mixture of alginate and water, and then will made impression of the patient's upper jaw according to the standard procedure.

Category

Prevention

2

Description

Before the impressions,the posterior areas of the patient's palate will be stained by gel-benzocaïen anesthesia4% and after 3 minutes impression will be made.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Vahid Fakhzade

Street address

Dental Faculty, Tabriz University of Medical Sciences

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology

Full name of responsible person

Sarvar Alipur

Street address

Tabriz- Golgasht avenue -Vice Chancellor for
Research and Technology

City

Tabriz

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research and Technology

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Vahid Fakhrazadeh

Position

PhD in prosthodontics

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

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Contact

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Full name of responsible person

Bahman Hoseinpur

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty