

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluating the effect of mouthwash containing pomegranate peel total extract on gag reflex during impression taking in patients referring to north Khorasan dental school

Protocol summary

Study aim

Determining the effect of mouthwash containing total pomegranate peel extract on gag reflex during impression

Design

A clinical trial with a control group that is the same as the intervention group, with parallel, double-blind, randomized, phase 2 groups on 40 patients. Excel software rand function was used for randomization.

Settings and conduct

40 patients referred to the dental school with a diagnosis of severe nausea reflex by Abslang and according to the Dickinson table grading was jointly selected in both treatment and control groups over a period of one week and participated in the study. While obtaining written consent and completing a pre-designed nausea reflex assessment questionnaire, one of the two available mouthwashes is randomly selected and applied in the first session and then molded by the molding material. Alginate will be taken and the results will be noted in the evaluation form while mentioning the desired mouthwash code.

Participants/Inclusion and exclusion criteria

1. Patients with severe nausea reflex due to stimulation of the salivary gland in the soft palate and tonsils
2. Patients' satisfaction to participate in the study:
1. Patients with underlying diseases
3. Patients with a psychologic background include fear, anxiety, previous risky treatment experience who experience nausea reflex or its consequences.

Intervention groups

The intervention and control groups use mouthwash and placebo in the same way and 40 people with a time difference of one week

Main outcome variables

Gag reflex rate, the rate of recovery from gag reflex

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210505051187N2**

Registration date: **2021-06-08, 1400/03/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-08, 1400/03/18**

Update count: **0**

Registration date

2021-06-08, 1400/03/18

Registrant information

Name

sahere soltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3222 2361

Email address

sahere.soltani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-03, 1400/02/13

Expected recruitment end date

2021-06-13, 1400/03/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of mouthwash containing pomegranate peel total extract on gag reflex during impression taking in patients referring to north Khorasan dental school

Public title

Effect of pomegranate peel mouthwash in treatment of gag reflex

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with severe gag reflex due to stimulation of the abeslang in the soft palate and tonsils Patients' satisfaction to participate in the study

Exclusion criteria:

Age

From **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize, simple randomization will be used by shuffling the card. In this way, the number 1 is assigned to the first group and the number 2 assigned to the second group. The number 1 is written on 15 cards and the number 2 is written on 15 cards, then the cards are merged (shuffled) and one card is removed and The allocation is recorded and then the card is returned to the card collection.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are aware of the type of intervention and will be given written consent. They only do not know about the drug and mouthwash, and the executors do not know about the mouthwash codes and the coding will be done by a technician and its analysis will be done by a statistical consultant.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of north khorasan university of medical science

Street address

Dr soltani office, ghiyam street, Telecommunication crossroads

City

Bojnourd

Province

North Khorasan

Postal code

9419118894

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.NKUMS.REC.1400.020

Health conditions studied

1

Description of health condition studied

Gag reflex

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Gag teflex rate

Timepoint

7 days after using the first bottle

Method of measurement

Dickinson gag reflex ranking table

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pomegranate peel whole mouthwash, 10%, 20 cc, 1 time, 40 seconds, spool Control group:

Category

Treatment - Drugs

2

Description

Control group: placebo mouthwash with permissible food color and taste similar to pomegranate peel full extarct mouthwash, 20 cc, 1 time, 40 seconds, reel

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

North Khorasan School of Dentistry

Full name of responsible person

Reza taghizade firouzjaie

Street address

North khorasan dentistry school

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Email

Rezataghizade123@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Sahereh soltani

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Arkan,north khorasan dental school

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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

Bojnourd University of Medical Sciences

Proportion provided by this source

70

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Reza taghizade firouzjail

Position

Scholar

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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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