

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of quercus extract on the gag reflex in dental patient

Protocol summary

Study aim

To prepare a drug to reduce the gag reflex during dental procedures

Design

The clinical trial has a control group of 40 people and an intervention group of 40 people. It is performed by the laboratory technician and the medicine and placebo are provided to the executors completely randomly.

Settings and conduct

The extraction site is located in the Biochemistry and Nutrition Research Center for Metabolic Diseases and the production site is located in Yas Confectionery, Aran and Bidgol Branches. The jaws and faces of Nikan and Di are from Kashan city. First, the severity of gags or the absence of gags in the tonsils and soft palate is measured by Abslang and the results are recorded as nausea, low, moderate, severe in the data collection form. To be. Each person is then given a placebo pill or oak extract by a third party. This study will be double-blind and the drug code will not be known to the therapist until after the statistical analysis. The lozenges are sucked by the people for 5 minutes until they are completely dissolved. After the intervention with oak extract or placebo, the tonsils and soft palate areas are examined by the examiner to check the severity of the gag and the data are recorded in the data collection form.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- History of gag experience in dentistry Exclusion criteria 1- Existence of any type of central and peripheral nerve lesions 2. Existence of any type of oral lesions 3. Taking any medicine 4- Suffering from gastrointestinal and respiratory diseases 5. Allergy to medicinal plants

Intervention groups

Candies containing 200 mg of oak extract as medicine and candies without extract containing sugar and water as a placebo are given to patients with gag.

Main outcome variables

Gag reflex

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012438N33**

Registration date: **2020-11-16, 1399/08/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-16, 1399/08/26**

Update count: **0**

Registration date

2020-11-16, 1399/08/26

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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taghizadeh_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of quercus extract on the gag reflex in dental patient

Public title

Investigation of the effect of oak extract (quercus) on nausea reflex

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

History of gag experience in dentistry

Exclusion criteria:

1- Existence of any type of central and peripheral nerve lesions
Existence of any type of oral lesions
Taking any medicine
Suffering from gastrointestinal and respiratory diseases
Allergy to medicinal plants

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The study will be a double-blind clinical trial on 80 patients referred to the radiology department. The clinical trial has a control group of 40 people and an intervention group of 40 people, double-blind, using a simple randomization method to randomize each candy. Are placed randomly in cellophane packaging and according to the identification of random numbers in the table of random numbers on the sample of candies, the coding is done by the laboratory technician and the medicine and placebo are provided to the executors. It becomes. Then the demographic information of the patients is prepared. And patients are randomly coded using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each of the candies is randomly placed in cellophane packaging and according to the identification of random numbers on the candy sample, the coding is done by the laboratory technician and the medicine and placebo are provided to the executors completely randomly. It should be noted that candies are matched in shape, color and weight.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Biomedical Research, Schools of Medicine and Dentistry, Kashan University of Med

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5th of Qotb -e Ravandi Blvd. P.O.Box: 87159-81151, Kashan, IRAN

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Province

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Postal code

8715981151

Approval date

2020-07-13, 1399/04/23

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.048

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

Gag reflex

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

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

Gag reflex

Timepoint

Before examination and 5 minutes after using candies containing oak and placebo extracts

Method of measurement

Before and 5 minutes after sampling by Abslang. Criteria for measuring the severity of nausea: No nausea: No gag during contact with high risk surfaces of the mouth such as soft palate and tonsils
Hakm: Gag formation during contact with high risk surfaces of the mouth such as soft palate and tonsils
Medium: Gag formation during contact with low levels Risk of mouth such as hard palate and hard floor: Creating a gag before contact with an abscess, such as when opening the mouth and seeing an abscess

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Recipient of candy containing oak extract

Category

Treatment - Drugs

2

Description

Control group: Recipient of candy without oak extract, containing water and sugar

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiology Center, School of Dentistry, Kashan
University of Medical Sciences

Full name of responsible person

Dr. Ameneh Taghdisi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Alireza Moraveji

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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

Kashan University of Medical Sciences

Proportion provided by this source

100

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohsen Taghizadeh

Position

full Profesor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Latest degree

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Other areas of specialty/work

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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