

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of *Elaeagnus Angustifolia* L. lozenge on gag reflex in dental patients who referred to Dental School of Isfahan University of Medical Science in 2007

Protocol summary

Summary

This study has been evaluated the effect of *Elaeagnus Angustifolia* lozenge in controlling gag reflex during dental treatment. This study was a Randomized double blind controlled trial with convenient sampling. Inclusion criteria: The basic requirements for admission were determined good cooperation; Fill a standard consent form (The patients who assigned criteria of the Helsinki Declaration entered in our study), Exclusion criteria: Patients with any central; peripheral nervous system lesions or oral lesions were excluded. Samples were selected from patients who referred to Radiology Department of Dental School of Isfahan University of Medical Sciences. 84 patients entered in each group of intervention (with *Elaeagnus Angustifolia* L. Extracts) or control (with placebo) by randomization procedure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105246578N1**
Registration date: **2011-08-15, 1390/05/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-15, 1390/05/24

Registrant information

Name

Elham Shadmehr

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1625 0955

Email address

elham.shadmehr@gmail.com

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science

Expected recruitment start date

2007-03-20, 1385/12/29

Expected recruitment end date

2008-03-19, 1386/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of *Elaeagnus Angustifolia* L. lozenge on gag reflex in dental patients who referred to Dental School of Isfahan University of Medical Science in 2007

Public title

Effect of *Elaeagnus Angustifolia* L. lozenge on gag reflex in dental patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: good cooperation; Fill and assigned standard consent form of criteria of the Helsinki Declaration, Exclusion criteria: Patients with any central nervous system lesions; any peripheral nervous system lesions; any oral lesions.

Age

From **10 years** old to **50 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Department of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

8174755153

Approval date

2008-07-22, 1387/05/01

Ethics committee reference number

387082

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

Degree of Gag Reflex severity

Timepoint

5 min after usage of placebo or lozenge

Method of measurement

Before and after intervention, gag reflex was evaluated by stimulation of soft palate and pharyngeal tonsils with Abslang.

Secondary outcomes

1

Description

Mouth anesthesia

Timepoint

5min

Method of measurement

stimulation of soft palate and tonsils

Intervention groups

1

Description

After determining the severity of Gag reflex, encoded lozenge (*Elaeagnus Angustifolia* lozenge) was given to each patient. This was done by a third person. After five minutes, the Gag reflex severity in the areas of soft palate and pharyngeal tonsils were evaluated again by the same examiner and the final results were recorded. Finally, the case group was distinguished by the code number from the control group.

Category

Treatment - Drugs

2

Description

After determining the severity of Gag reflex, encoded lozenge (placebo lozenge) was given to each patient. This was done by a third person. After five minutes, the Gag reflex severity in the areas of soft palate and pharyngeal tonsils were evaluated again by the same examiner and the final results were recorded. Finally, the control group was distinguished by the code number from the case group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical Sciences, Radiology Department

Full name of responsible person

Dr. Ehsan Hekmatian

Street address

Isfahan University of Medical Sciences, Dental School

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Department of Isfahan University of Medical Sciences

Full name of responsible person

Tavangar Mr.

Street address

Dental School, Isfahan University of Medical Sciences.

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Department of Isfahan University of Medical Sciences

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**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Ehsan Hekmatian

Position

Assistant professor of maxillofacial radiology, Isfahan University of Medical Sciences

Other areas of specialty/work**Street address**

Isfahan University of Medical Sciences

City

Isfahan

Postal code

87986546

Phone

+98 913 327 2159

Fax**Email**

hekmatian@dnt.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Assistant professor of maxillofacial radiology, School of Dentistry, Isfahan University of medical s

Full name of responsible person

Dr. Ehsan Hekmatian

Position

Assistant professor of maxillofacial radiology, school of dentistry, Esfahan University of medical s

Other areas of specialty/work**Street address**

Isfahan University of Medical Sciences

City

Isfahan

Postal code**Phone**

+98 913 327 2159

Fax**Email**

hekmatian@dnt.mui.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

School of Pharmacy , Isfahan University of Medical Sciences

Full name of responsible person

Dr.Gholamreza Asghari

Position

Professor of pharmacognosy

Other areas of specialty/work**Street address**

School of pharmacy , Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Postal code**Phone****Fax****Email****Web page address**

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