Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Effect of Punica L. lozenge on gag reflex in dental patients

Protocol summary

Summary
This study has been evaluated the effect of Punica L. 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 Punica L. Extracts) or control (with placebo) by randomization procedure. Gag reflex was evaluated by abslung stimulation before and after using placebo and lozenge.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201108126578N2**
Registration date: **2011-09-22, 1390/06/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2011-09-22, 1390/06/31

Registrant information
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Recruitment status
Recruitment complete

Funding source
Research Department of Isfahan University of Medical Sciences

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 Punica L. lozenge on gag reflex in dental patients

Public title
Effect of Punica 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

Approval date
2008-08-21, 1387/05/31

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 sevierity

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 sevierity of Gag reflex,encoded lozenge (Punica L. lozange) 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 distincted by the code number from the control group.

Category
Placebo

2

Description
After determining the sevierity of Gag reflex,encoded lozenge (plaecebo lozang) 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 distincted 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

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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