

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Preparation and clinical trial of tooth paste contained *Pistacia atlantica* subsp. *mutica* oleo-gum resin, *Punica granatum* var. *pleniflora* flowers and *Eugenia caryophyllata* buds for halitosis

Protocol summary

Summary

The aim of this study is to evaluating effect of a toothpaste contained mastic resin, pomegranate and clove oil and clinical assessment of oral malodor. Exclusion criteria are systemic diseases, use of antibiotics and drugs causing dry mouth. This double blind study possesses the assessment of plaque and bleeding and halitosis factors at the beginning as well as end of 2 weeks application of tooth paste twice a day administration. The results will be analyzed according to statistical assesses.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030921395N1**
Registration date: **2016-08-30, 1395/06/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-30, 1395/06/09

Registrant information

Name

Atefeh Arabzadeh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3242 4128

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2017-01-01, 1395/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation and clinical trial of tooth paste contained *Pistacia atlantica* subsp. *mutica* oleo-gum resin, *Punica granatum* var. *pleniflora* flowers and *Eugenia caryophyllata* buds for halitosis

Public title

Effect of *Pistacia atlantica* subsp. *mutica* oleo-gum resin, *Punica granatum* var. *pleniflora* flowers and *Eugenia* on halitosis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Organoleptic score ≥ 2 ; Tongue coating score ≥ 4 exclusion criteria: smoking; alcohol; systemic disease; medicinal causing dry month; use of antibiotics in the past month; Eating spicy foods, onions and garlic in the 48 hours prior to the examination; Using orthodontic appliance (fixed and mobile) and mobile dentures; diabetes; metabolic disease; infections of the upper respiratory tract; kidney and liver failure, chronic inflammatory diseases; surgery of the head and neck malignancies; anticoagulation therapy such as aspirin; heparin; warfarin.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

1

Registry name

معاونت پژوهشی و فناوری دانشگاه علوم پزشکی شیراز

Secondary trial Id

C.T-9375-7245

Registration date

1393-08-01, 773/01/-231

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor for Research, Shiraz University of
Medical Sciences

Street address

Zand Blvd., Shiraz, Iran

City

Shiraz

Postal code

71345-1978

Approval date

2014-10-23, 1393/08/01

Ethics committee reference number

C.T-9375-7245

Health conditions studied

1

Description of health condition studied

Halitosis

ICD-10 code

R19.6

ICD-10 code description

Halitosis

Primary outcomes

1

Description

Halitosis

Timepoint

2 weeks

Method of measurement

plaque index, bleeding index and halitosis check list

Secondary outcomes

1

Description

microbial contamination

Timepoint

2 weeks

Method of measurement

microbial contamination of salivary

2

Description

aproximal plaque index

Timepoint

2 weeks

Method of measurement

aproximal plaque index

3

Description

tounge coating

Timepoint

2 weeks

Method of measurement

tounge coating

4

Description

sulcus bleeding index

Timepoint

2 weeks

Method of measurement

sulcus bleeding index

Intervention groups

1

Description

herbal toothpaste have been used for two weeks in oral cavity.

Category

Treatment - Drugs

2

Description

placebo is used in oral cavity for 2 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry faculty of shiraz university of medical sciences

Full name of responsible person

Dr Mostafa Rezaei

Street address

Dentistry faculty, Ghomabad, Ghasrodasht street, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Basir Hashemi

Street address

Research vice, 7th floor, Central building of Shiraz University of Medical sciences, Zand street, Shiraz

City

Shiraz

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 of Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Atefeh Arabzadeh

Position

PhD candidate of Traditional Pharmacy

Other areas of specialty/work

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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