

# 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)

###### Phone

+98 71 3242 4128

###### Email address

arabzade\_a@sums.ac.ir

##### 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  $\geq 2$ ; Tongue coating score  $\geq 4$  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

#### Street address

Department of Traditional Pharmacy, School of Pharmacy, Karafarin Street, Shiraz

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences PhD candidate of Traditional Pharmacy

#### Full name of responsible person

Abdolali Mohagheghzadeh

#### Position

Head of Department

#### Other areas of specialty/work

#### Street address

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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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#### Position

PhD candidate in traditional pharmacy

#### Other areas of specialty/work

#### Street address

Dep. of Traditional Pharmacy, School of of Pharmacy, Karafarin Street, Shiraz

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**Email**

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**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*