Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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 ≥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
Street address
Department of Traditional Pharmacy, School of Pharmacy, Karafarin Street, Shiraz
City
Shiraz
Postal code
7194654833
Phone
+98 71 3242 4128
Fax
+98 71 3242 4126
Email
arabzade_a@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical SciencesPhD candidate of Traditional Pharmacy
Full name of responsible person
Abdolali Mohagheghzadeh
Position
Head of Department
Other areas of specialty/work
Street address
Department of Traditional Pharmacy, School of Pharmacy, Karafarin Street, Shiraz
City
Shiraz
Postal code
71345-1583
Phone
+98 917 300 0668
Fax
+98 71 3242 4126
Email
Mohaghegh@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Atefeh Arabzadeh
Position
PhD candidate in traditional pharmacy
Other areas of specialty/work
Street address
Dep. of Traditional Pharmacy, School of of Pharmacy, Karafarin Street, Shiraz
City

Shiraz
Postal code
Phone
+98 71 3242 4128
Fax
+98 71 3242 4126
Email
arabzade_a@sums.ac,ir
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