Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effectiveness of mouthwashes containing green tea on the severity of halitosis in patients with halitosis

Protocol summary

Summary

This study is of clinical trials to determine the effect of mouthwashes containing green tea extract on the severity of halitosis in patients with this problem. A total of 42 patients with oral malodor referred to Department of Periodontics, School of Dentistry, Isfahan University of Medical Sciences were first examined clinically, and when approved the disease, included in the study. Smoking patients and those with systemic diseases considered as confounding factors in the study were excluded and replaced. Patients enrolled in the study were divided into two intervention (21 individuals) and control groups (21 individuals) based on a table of random numbers and in the form of double-blind trial (scholars and patients). The severity of halitosis was determined in both groups by organoleptic method. Patients in the intervention group and those in the control group used the mouthwash containing green tea and the placebo, respectively, twice a day (morning and late at night) each time for 30 seconds, for a week. Patients were trained the modified brushing Bass technique in order to eliminate the confounding factors. The intensity of halitosis was re-measured in patients using organoleptic method, and its changes were compared with the primary state. The improvement was expected in the severity of halitosis in both the intervention and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012026122N1**
Registration date: **2016-02-25, 1394/12/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-25, 1394/12/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-02-27, 1394/12/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of mouthwashes containing green tea on the severity of halitosis in patients with halitosis

Public title

Comparison of the effectiveness of mouthwashes containing green tea on the severity of halitosis in patients with halitosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who complain of oral malodor; Patients who their halitosis will be confirmed after clinical examination. Exclusion criteria: Patients who were not willing to participate in the study; female patients in their period of menstruation; smoking people; those with systemic diseases.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar jarib street, Isfahan, Iran

City

Isfahan

Postal code

8174673461

Approval date

2014-12-22, 1393/10/01

Ethics committee reference number

394501

Health conditions studied

1

Description of health condition studied

oral malodor

ICD-10 code

R19.6

ICD-10 code description

halitosis

Primary outcomes

1

Description

oral halitosis with organoleptic method

Timepoint

before intervention, one weak after intervention

Method of measurement

Fundamentals of Organoleptic method: The patient will be asked to keep his/her mouth closed for two minutes and then exhale out the air. To determine the severity of the oral malodor, the researcher will measure the severity of the patient's halitosis from the distance of 10 cm. and 50 cm., and then the severity of patient's halitosis is classified as following five categories based on the organoleptic method: 0 = no smell of halitosis, 1= low, 2= moderate, 3= severe, 4 = very intense smell

Secondary outcomes

empty

Intervention groups

1

Description

using from green tea mouth wash for one week two times a day in intervention group

Category

Treatment - Drugs

2

Description

using placebo mouth wash for one week two times a day in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontics Department of School of Dentistry, Isfahan University of Medical Sciences

Full name of responsible person

Parichehr Behfarnia

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School of Dentistry, Isfahan University of Medical Sciences, Hezarjarib street, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chanceller of Isfahan University of Medical Sciences
Full name of responsible person
Dr. Mehdi Nematbakhsh
Street address
Isfahan University of Medical Sciences, Hezarjarib street, Isfahan
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Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chanceller 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