

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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

###### Name

Parichehr Behfarnia

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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###### Email address

behfarniaa@dnt.mui.ac.ir

##### 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 week 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

##### **Street address**

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

##### **City**

Isfahan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor of Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Mehdi Nematbakhsh

**Street address**

Isfahan University of Medical Sciences, Hezarjarib street, Isfahan

**City**

Isfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor 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

**Contact****Name of organization / entity**

Isfahan University of Medical Science

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Parichehr Behfarnia

**Position**

Department of Periodontics and Torabinejad Research Center, School of Dentistry, Isfahan University

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## Person responsible for scientific inquiries

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Periodontist, Assistant Professor

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## Person responsible for updating data

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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*