

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effect of sage plant extract (*salvia officinalis*) gel on dental plaque streptococcus mutans microorganism and periodontal indexes.

#### Protocol summary

##### Summary

Objective: effect of sage plant extract (*salvia officinalis*) gel on dental plaque streptococcus mutans microorganism and periodontal indexes. A double blind clinical trial study was conducted on 70 students (35 girl/35 boy) (aged 11-12 years) with same systemic, socioeconomic condition, oral hygiene, periodontal condition (BOP-/pocket probing mm $\geq$ 3/without attachment loss) and plaque index. Individuals that used any antibiotics or mouthwash and toothpaste containing antibacterial components were excluded from this study. These students were randomly divided into two groups. The first group (35 students) was given the dental gel with sage extracts and the second group (35 students) was given the placebo gel (without sage extract and any antibacterial or anti-inflammatory components with same color and odor). Dental plaque microorganisms that obtained from buccal surfaces were entered in BHI 1cc medium and then cultured in MSB medium immediately. PI, GBI and the number of streptococcus mutans colonies was measured in the first and 30 days later. Before starting therapy all subjects are given a same hygienic kit includes toothbrush, toothpaste, floss and test or control gel and correct manner of brushing instructed them.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012070710204N1**

Registration date: **2012-08-31, 1391/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-08-31, 1391/06/10

#### Registrant information

##### Name

Maryam Beheshti Rouy

##### Name of organization / entity

Hamadan university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1827 1984

##### Email address

m.beheshti@umsha.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Hamadan University of Medical Sciences

#### Expected recruitment start date

2012-06-16, 1391/03/27

#### Expected recruitment end date

2012-08-17, 1391/05/27

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of sage plant extract (*salvia officinalis*) gel on dental plaque streptococcus mutans microorganism and periodontal indexes.

#### Public title

Effect of sage extract on caries and periodontal problems control.

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

inclusion criteria: subjects with same systemic, socioeconomic condition, oral hygiene, periodontal condition (BOP-/pocket probing mm $\geq$ 3/without

attachment loss)and plaque index were included in this study. exclusion criteria: individuals that used any antibiotics or mouthwash and toothpaste containing antibacterial components were excluded from this study.

#### **Age**

From **12 years** old to **14 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **70**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Single

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

##### **Ethics committee**

###### **Name of ethics committee**

Hamadan University of Medical Sciences Ethics Committee

###### **Street address**

Hamadan. Shahid Fahmideh ave. Opposite of Mardom park

###### **City**

Hamadan

###### **Postal code**

65178-38677

###### **Approval date**

2012-06-16, 1391/03/27

###### **Ethics committee reference number**

16/35/9/1010/د/پ

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

dental caries and periodontal diseases

##### **ICD-10 code**

Y56.7

##### **ICD-10 code description**

Dental drugs, topically applied

### **Primary outcomes**

#### 1

##### **Description**

microorganism count in medium

##### **Timepoint**

at beginning of study and 30 days later

##### **Method of measurement**

visual counting of microorganism in medium

#### 2

##### **Description**

PI

##### **Timepoint**

at beginning of study and 30 days later

##### **Method of measurement**

visual estimating of PI

#### 3

##### **Description**

GBI

##### **Timepoint**

at beginning of study and 30 days later

##### **Method of measurement**

visual estimating GBI

### **Secondary outcomes**

#### 1

##### **Description**

caries

##### **Timepoint**

at the first and 6 month later

##### **Method of measurement**

visual and radiographical assessment of caries

#### 2

##### **Description**

gingivitis

##### **Timepoint**

at the first and 6 month later

##### **Method of measurement**

checking of gingivitis signs with BOP,PI,GBI ind

### **Intervention groups**

#### 1

##### **Description**

In the intervention group, subjects rub the sage gel with finger fine as the half size of toothbrush head on teeth and adjacent gingiva after complete brushing every night for 30 nights.

##### **Category**

Treatment - Drugs

## 2

### Description

In the control group, subjects rub the placebo gel with finger fine as the half size of toothbrush head on teeth and adjacent gingiva after complete brushing every night for 30 nights.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Welfare organization

##### Full name of responsible person

##### Street address

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamadan University of Medical Sciences.Vice  
Chancellor for Research and Technology

##### Full name of responsible person

Dr Heydar Tavilani

##### Street address

Hamadan, Shariati ave, Shahid Fahmideh blv,  
Hamadan Dental Faculty.Vice Chancellor for Research  
and Technology

##### City

Hamadan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Hamadan University of Medical Sciences.Vice Chancellor  
for Research and Technology

#### 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

Hamadan University of Medical Sciences

#### Full name of responsible person

Dr Maryam Beheshti Rouy

#### Position

Assistant professor

#### Other areas of specialty/work

#### Street address

Hamadan Dental Faculty

#### City

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m.beheshti@umsha.ac.ir; beheshtirouym@yahoo.com

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Dr Amin Khodadoustan

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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*