

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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 mm3 $\geq$ /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

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Maryam Beheshti Rouy

Name of organization / entity

Hamadan university of medical sciences

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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 mm3 $\geq$ /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

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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