

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of anti-plaque and anti-inflammatory effects of sage (*Salvia Officinalis*) herbal mouthwash with chlorhexidine

Protocol summary

Study aim

Comparison of anti-plaque and anti-inflammatory effects of sage (*Salvia Officinalis*) herbal mouthwash with chlorhexidine

Design

This study is a double-blind clinical trial in a parallel design. The study population will include all patients referred to the School of Dentistry, Islamic Azad University of Isfahan. 63 eligible people will be selected conveniently. Simple randomization is used for randomization and participants are assigned to three intervention groups.

Settings and conduct

This study will be performed in the School of Dentistry of the Islamic Azad University of Isfahan. In this double-blinded study, the researcher and the patient will keep blind to the allocation of study groups and the type of drug received. After health education for patients, mouthwash will be provided to patients by the project partner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-65; At least 20 teeth with moderate inflammation
Exclusion criteria: Patients with any systemic disease; Pregnant and breastfeeding women; People who have taken any antibiotics in the last six months or are allergic to any type of antibiotic; People who have had scaling and gum surgery in the last six months; Smokers

Intervention groups

In the first intervention group, patients are asked to rinse 10 ml of mouthwash around their mouth for about 1 minute twice a day for 2 weeks (morning and night and expel it). In the second intervention group, patients are asked to spin 10 ml of mouthwash (2% chlorhexidine 2) in their mouth twice a day (morning and night) for 2 weeks and excrete it. In the third intervention group, patients are asked to spin 10 ml of mouthwash (*Salvia*) in their mouth twice a day (morning and night) for 2 weeks and excrete it

Main outcome variables

Inflammation of the gums, plaque index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N183**

Registration date: **2022-02-19, 1400/11/30**

Registration timing: **prospective**

Last update: **2022-02-19, 1400/11/30**

Update count: **0**

Registration date

2022-02-19, 1400/11/30

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-04-30, 1401/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of anti-plaque and anti-inflammatory effects of sage (Salvia Officinalis) herbal mouthwash with chlorhexidine

Public title
Comparison of the effects of sage (Salvia Officinalis) herbal mouthwash with chlorhexidine

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20-65 At least 20 teeth with moderate inflammation
Exclusion criteria:
Patients with any systemic disease Pregnant and breastfeeding women People who have taken any antibiotics in the last six months or are allergic to any type of antibiotic People who have had scaling and gum surgery in the last six months Smokers

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **63**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization. 62 cards will be selected and two-digit, three-digit and four-digit numbers will be inserted on them, and after selecting the cards by the project partner, patients will be placed in the first, second and third intervention groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
All three mouthwashes will be provided to patients in the same package and in coded form. Researchers and patients were kept blind to the type of mouthwash and the allocation of intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University (Isfahan Branch)

Street address

University Blvd, Arghavaniyeh, East Jay St.

City

Esfahan

Province

Isfahan

Postal code

8155139998

Approval date

2021-12-22, 1400/10/01

Ethics committee reference number

IR.IAU.KHUISF.REC.1400.295

Health conditions studied

1

Description of health condition studied

Inflammation of the gums

ICD-10 code

K05.0

ICD-10 code description

Acute gingivitis

Primary outcomes

1

Description

Inflammation of the gums

Timepoint

Start of study and end of study (after two weeks)

Method of measurement

Physician examination

2

Description

Plaque index

Timepoint

End of study (after two weeks)

Method of measurement

Physician examination

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group, patients are asked to rinse

10 ml of mouthwash around their mouth for about 1 minute twice a day for 2 weeks (morning and night and expel it.

Category

Treatment - Other

2

Description

In the second intervention group, patients are asked to spin 10 ml of mouthwash (2% chlorhexidine 2) in their mouth twice a day (morning and night) for 2 weeks and excrete it.

Category

Treatment - Other

3

Description

. In the third intervention group, patients are asked to spin 10 ml of mouthwash (Salvia) in their mouth twice a day (morning and night) for 2 weeks and excrete it

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Islamic Azad University of Isfahan

Full name of responsible person

Dr. Vahid Esfahanian

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University Blvd, Arghavaniyeh, East Jay St.

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vahid.esfahanian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Vahid Esfahanian

Position

Faculty member of Esfahan Free University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Vahid Esfahanian

Position

Faculty member of Esfahan Azad University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr. Vahid Esfahanian

Position

Faculty member of Esfahan Azad University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available