

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Evaluation of sumac (rhus coriaria) mouthwash effects as a adjuvant treatment in patients with gingivitis

Protocol summary

Study aim

The effects of sumac (rhus coriaria) mouthwash as adjuvant treatment in patients with gingivitis

Design

I trial has a control group, with parallel groups, double-blind

Settings and conduct

zahedan dental school

Participants/Inclusion and exclusion criteria

Patients with at least 20 teeth Index of gingival inflammation and gingival bleeding with a minimum code of 13 No smoking No history of antibiotic use in the past three months Not using orthodontic devices or removable prosthesis Willingness to enter the study No history of sensitivity to various mouthwashes Not having oral diseases (pemphigus-lichen planus, etc.) Not using mouthwash according to the protocol noPregnancy and breastfeeding no Smoking or opium no Taking antibiotics, corticosteroids or non-steroidal anti-inflammatory drugs during the study period no Use of mouthwash in the last three months no Suffering from acute or chronic dental or periodontal infection and abscess and periodontitis, salivary gland disorders such as Sjogren's, stone, infection, no neoplasm, history of radiotherapy

Intervention groups

Control - placebo user - sumac mouthwash user

Main outcome variables

gingival inflammation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191012045067N9**

Registration date: **2023-08-24, 1402/06/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-24, 1402/06/02**

Update count: **0**

Registration date

2023-08-24, 1402/06/02

Registrant information

Name

masoomeh shirzaiy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3321 1135

Email address

shirzaiy@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of sumac (rhus coriaria) mouthwash effects as a adjuvant treatment in patients with gingivitis

Public title

Evaluation of sumac (rhus coriaria) mouthwash effects as a adjuvant treatment in patients with gingivitis

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with at least 20 teeth Index of gingival inflammation and gingival bleeding with a minimum code of 13 no smoking No history of antibiotic use in the past three months Not using orthodontic appliances or removable prosthesis Willingness to enter the study No history of sensitivity to various mouthwashes Not having oral diseases (pemphigus-lichen planus, etc.) using mouthwash according to the protocol no Pregnancy and breastfeeding no Smoking or opium no Taking antibiotics, corticosteroids or non-steroidal anti-inflammatory drugs during the study period no Use of mouthwash in the last three months no Having an acute or chronic dental or periodontal infection and abscess and periodontitis, salivary gland disorders such as Sjogren's, stone, infection, neoplasm, history of radiotherapy

Exclusion criteria:
Unwillingness to continue cooperation Age over 30 years

Age
From **20 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of participants to studied groups is done by simple randomization method. In this way, the samples of eligible clients are assigned to the desired group based on blocks of 4 (consisting of two groups A and B and two repetitions for each) that will be randomly selected from among all the possible states of permutations. These blocks were created using statistical software R version 4.0.2

Blinding (investigator's opinion)
Double blinded

Blinding description
patient and analyzer don't know about drugs and placebo also which one is drug and which one is placebo The participant and analyzer do not know the type of consumables and the consumables are numbered as 1 , 2,3. The substance is given to the participant in a glass with a coding matte lid and the analyzer records information only based on the desired code

Placebo
Used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Dental School, Azadegan Street

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98176996930

Approval date

2023-06-18, 1402/03/28

Ethics committee reference number

IR.ZAUMS.REC.1402.124

Health conditions studied

1

Description of health condition studied

gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

Inflammation of gingiva

Timepoint

Before using mouthwash and one week after using mouthwash

Method of measurement

bleeding on probing

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, a person rinses 15 cc of sumac (combination of 20 cc sumac powder extract and flavoring) mouthwash twice a day every time for 5 minutes for 1 week.

Category

Treatment - Drugs

2

Description

Intervention group 2-normal saline: In this group, the person rinses 15 cc of normal saline mouthwash twice ready a day every time for 5 minutes for 1 week. .

Category

Placebo

3

Description

Intervention group 3 (control) - Chlorhexidine: In this group, a person rinses 15 cc of Chlorhexidine mouthwash (100 cc ready-made bottle) twice a day every time for 5 minutes for 1 week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Dental School

Full name of responsible person

Masoomeh Shirzaiy

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Dental School, Azadegan Street

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+98 54 3344 1814

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shirzaiy@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Somaye Ansari Moghaddam

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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

Zahedan University of Medical Sciences

Proportion provided by this source

1

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Masoomeh Shirzaiy

Position

Faculty

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Faculty

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

Dentistry

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Dental School, Azadegan Street-Zahedan

City

Zahedan

Province

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 further 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