

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Teucrium polium mouth-wash effect on salivary Mutans streptococci

Protocol summary

Summary

This study is a Double-Blind Randomized Crossover Clinical Trial that will be done on 22 students of Rafsanjan Dental School, who meet the inclusion criteria. First, mouthwash with 25% concentration of Teucrium polium (TP) is provided. The volunteers will randomly be divided into two groups, the first group will take TP mouthwash and the second group will take placebo. Volunteers will use 15cc of mouthwash for two weeks, and twice a day, and each time for 30 seconds in the oral cavity and will not drink and not rinse mouth until 30min. At 10 am, two cc of saliva without any provocation by spitting will be collected in a sterile tube. Patients then entered a period of three weeks Washout (no mouthwash or placebo). Again, saliva will be collected. In the second stage, the first group will receive placebo and the second group will take TP mouthwash for two weeks. After this point saliva samples will be collected. Streptococcus mutans counts in saliva samples will be done in the microbiology laboratory.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121815842N1**

Registration date: **2014-06-16, 1393/03/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-16, 1393/03/26

Registrant information

Name

Somayeh Khoramian Tusi

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3353 1614

Email address

dr.khoramian@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Teucrium polium mouth-wash effect on salivary Mutans streptococci

Public title

Teucrium polium mouth-wash effect on dental caries prevention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: not using antibiotics in the past month; optimal oral health (dental plaque index smaller or equal to 20%); lack of Orthodontic Appliances
Exclusion criteria: using antibiotics in the past month; poor oral health (dental plaque index larger than 20%); having Orthodontic Appliances

Age

From **18 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 22

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Rafsanjan University of Medical Sciences

Street address

Rafsanjan University of Medical Sciences, Imam Ali street, Rafsanjan, Kerman

City

Rafsanjan

Postal code

7717933777

Approval date

2014-05-22, 1393/03/01

Ethics committee reference number

315/9/31 پ

Health conditions studied**1****Description of health condition studied**

Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes**1****Description**

salivary Mutans streptococci count

Timepoint

before intervention /2weeks after intervention/ before the second intervention/2weeks after the second intervention

Method of measurement

count of colonies in culture

Secondary outcomes

empty

Intervention groups**1****Description**

intervention group: 15 cc Teucrium polium mouth-wash 2weeks/ twice a day, and each time for 30 seconds swish in oral cavity

Category

Treatment - Drugs

2**Description**

control group: mouth-wash contains distilled water instead of TP 15 cc placebo 2weeks/ twice a day, and each time for 30 seconds swish in oral cavity 15 cc mouth-wash 2weeks/ twice a day, and each time for 30 seconds swish in oral cavity

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rafsanjan Dental School

Full name of responsible person

Somayeh Khoramian Tusi

Street address

Rafsanjan Dental School, Mofateh street, Rafsanjan, Kerman

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Hamid Hakimi

Street address

Rafsanjan University of Medical Sciences, Imam Ali street, Kerman, Rafsanjan

City

Rafsanjan

Grant name

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

Yes

Title of funding source
Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Somayeh Khoramian Tusi

Position

Dean/Assistant professor of Rafsanjan Dental School

Other areas of specialty/work

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Pediatric dentist

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Web page address

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