Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of Zataria multiflora and Propolis mouthwash effect on Streptococcus mutans and Lactobacillus in saliva and dental biofilm

Protocol summary

Study aim

In this study, after preparing the mouthwash containing the extract of both mentioned substances and ensuring its quality and performing microbial and cell vitality tests in order to determine the anti-caries and anti-biofilm properties, we will investigate the effect of this mouthwash on the that cause tooth decay and compare it with CHX mouthwash on 150 volunteers and the final formulation will be presented as a laboratory mouthwash.

Design

In this study, the blinding process for the participants will be done by similarization mouthwashes prepared in black containers without labels will be used for the participants so that the participants do not know the type of substance used. The prepared samples will also be sent to the microbiologist in coded form without knowing the intervention group or gold standard. The method of random allocation of people will be the method of random blocks of 4.

Settings and conduct

Tabriz faculty of dentistry

Participants/Inclusion and exclusion criteria

from healthy people over 18 years of age and without any underlying disease and without any active disease in the oral cavity such as caries and inflammation of the gums and periodontium, who are not taking antibiotics or other drugs during the study process, and who can voluntarily avoid oral hygiene for one day, samples will be taken. Also, people should not have any removable or fixed orthodontic appliance in their mouth and should not use RPDs. If for any reason the person refuses or is unable to continue the study process, he/she will be excluded from the study.

Intervention groups

Three intervention groups (prescribing propolis mouthwash,Zataria Multiflora and Z.M+P), CHX (gold standard) and distilled water (control)

Main outcome variables

The number of colonies of Streptococcus mutans and Lactobacillus cultured from the samples

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240429061587N1**
Registration date: **2024-07-19, 1403/04/29**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-19, 1403/04/29**
Update count: **0**

Registration date

2024-07-19, 1403/04/29

Registrant information

Name

Dara Fazlzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 613 1428

Email address

fazlzade@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-09, 1403/02/20

Expected recruitment end date

2024-07-21, 1403/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of Zataria multiflora and Propolis mouthwash effect on Streptococcus mutans and Lactobacillus in saliva and dental biofilm

Public title
Evaluation of Zataria multiflora and Propolis mouthwash effect on Streptococcus mutans and Lactobacillus in saliva and dental biofilm

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
18 year old volunteers without systemic conditions without active oral cavity disease such as caries or periodontal disease able to stop oral hygiene maintenance for one day without using fixed or removable orthodontic appliance or removable partial denture

Exclusion criteria:
Having an underlying disease or an active disease in the oral cavity Use of fixed or removable orthodontic appliance or removable prosthesis Unwillingness to participate in the study Being under 18 years of age

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of random allocation of people will be the method of random blocks of 4. After collecting the volunteers to participate in the study, by using random allocation online sites and entering the data of the individuals, the allocation of the volunteers to each of the studied groups will be done.

Blinding (investigator's opinion)
Double blinded

Blinding description
The blinding process for the participants will be done by similarization: propolis, Shirazi thyme, propolis + Shirazi thyme and chlorhexidine mouthwashes prepared in black containers without labels will be used for the participants, so that the participants Do not know the type of material used. The prepared samples will also be sent to the microbiologist in coded form without knowing the intervention group or gold standard. Finally, the samples will be sent to the laboratory for microbial culture evaluation and analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The specialized committee of ethics in biomedical research

Street address
South Sheikh Bahai St, Mollasadra St,Vanak Square

City
Tehran

Province
Tehran

Postal code
1435916471

Approval date
2023-12-29, 1402/10/08

Ethics committee reference number
IR.BMSU.BAQ.REC.1402.090

Health conditions studied

1

Description of health condition studied
Tooth decay-causing microorganisms in saliva and teeth biofilm

ICD-10 code
K02

ICD-10 code description
Dental caries

Primary outcomes

1

Description
The amount of dental caries-causing microorganisms in saliva and dental biofilm

Timepoint
Before and after mouthwash and one week after using mouthwash

Method of measurement
Cultivation and colony counting

Secondary outcomes

empty

Intervention groups

1

Description
Prescribing propolis mouthwash
Category
Prevention

2

Description
Intervention group: Prescribing Zataria Multiflora mouthwash
Category
Prevention

3

Description
Intervention group: Prescribing propolis + Zataria Multiflora mouthwash
Category
Prevention

4

Description
Intervention group: Prescribing CHX mouthwash(gold standard)
Category
Prevention

5

Description
Control group: Prescribing distilled water
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz faculty of dentistry
Full name of responsible person
Dara Fazlzade
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
10
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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dara Fazlzade
Position
Dentist
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The mentioned items will be provided

When the data will become available and for how long

one year

To whom data/document is available

researchers

Under which criteria data/document could be used

university demand

From where data/document is obtainable

Baqiyatallah University of Medical Science

What processes are involved for a request to access data/document

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Comments