Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effects of licorice extract gel and 0.2% chlorhexidine mouthwash on the amount of Streptococcus mutans in saliva.

Protocol summary

Study aim
Comparison of salivary Streptococcus mutans species density in two groups of chlorhexidine mouthwash and licorice extract

Design
Single-group, single-blind, randomized controlled clinical trial on 60 patients.

Settings and conduct
60 patients with dental caries referred to the Oral Diseases Department of Tabriz Dental School will be randomly divided into two groups (30 people in each group). Licorice plant gel will be used in the intervention group and mouthwash containing 0.2% chlorhexidine will be used in the control group. . Quantification of Streptococcus mutans species in saliva samples of patients will be done using culture method. Mouthwash and gel will be poured into bottles. The evaluator of the number of Streptococcus mutans colonies in the saliva sample will not be aware of the grouping method (one-sided blind).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range from 18 to 55 years Good oral hygiene (using SOHI (simplified oral hygiene index) based on DIS (debries index) and CIS (calculus index). Based on this index, which includes the sum of CIS and DIS index, oral hygiene is from zero to number 6 Good health in this index is equal to the interval between zero and 1/2. Patients with average DMFT index above 2 (high-risk caries) Patients willing to participate in the study Exit criteria pregnancy high blood pressure a smoker Severe periodontal disease Patients who have taken antibiotics 2 weeks before the intervention. Patients who take antibiotics during the study. Patients who are allergic to licorice or it is harmful to them.

Intervention groups
Intervention group: mouthwash containing licorice extract gel will be used. Control group: 0.2% chlorhexidine mouthwash will be used.

Main outcome variables
Measuring of Streptococcus mutans microbial load in saliva

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200919048756N7**
Registration date: **2023-09-11, 1402/06/20**
Registration timing: **prospective**

Last update: **2023-09-11, 1402/06/20**
Update count: **0**

Registration date
2023-09-11, 1402/06/20

Registrant information

Name
Solmaz Maleki Dizaj

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3335 3161

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-06, 1402/07/14

Expected recruitment end date
2024-10-05, 1403/07/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effects of licorice extract gel and 0.2% chlorhexidine mouthwash on the amount of Streptococcus mutans in saliva.

Public title
Comparing the effects of licorice extract gel and 0.2% chlorhexidine mouthwash on the amount of Streptococcus mutans in saliva.

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age range from 18 to 55 years good oral hygiene (using SOHI (simplified oral hygiene index) Patients willing to participate in the study

Exclusion criteria:
pregnancy high blood pressure being a smoker Severe periodontal disease Patients who have taken antibiotics 2 weeks before the intervention Patients who take antibiotics during the study Patients who are allergic to licorice or it is harmful to them

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
60 patients are placed in two intervention and control groups using the randomization method of coin toss (tap and line) in such a way that one group is considered tap and the other group is considered line and based on the desired sample size, the same The number of coins is thrown and people are assigned to two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Mouthwash and gel will be poured into bottles. The active form of chlorhexidine mouthwash prepared for the control group is chlorhexidine hydrochloride. The evaluator of the number of Streptococcus mutans colonies in the saliva sample will not be aware of the grouping method (one-sided blind).

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Golgasht St, Daneshgah Ave, Tabriz University of Medical Sciences, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2023-08-07, 1402/05/16

Ethics committee reference number
IR.TBZMED.REC.1402.345

Health conditions studied

1

Description of health condition studied
Infection or inflammation of the oral environment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Reducing the microbial load of saliva

Timepoint
Saliva sampling will be done in two stages: one stage before starting to consume the formulations (extract and mouthwash) and the second sampling at the end of one week after consuming the formulations.

Method of measurement
The prepared saliva samples are sent to the microbiology laboratory of Tabriz University of Medical Sciences to count the colonies by a microbiologist.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: use of licorice extract mouthwash

Category

Prevention

2

Description
Control group: Chlorhexidine mouthwash 2%
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Tabriz University of Medical Sciences
Full name of responsible person
دکتر پریا مطهری
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Golgasht St, Tabriz University of Medical Sciences, Central Building No. 2 / Third Floor, Vice Chancellor for Research and Technology
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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
Tabriz University of Medical Sciences
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
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data will be published as an article.

When the data will become available and for how long

After the final publication of the article resulting from the data.

To whom data/document is available

Public

Under which criteria data/document could be used

For use in research articles and systematic reviews with citation.

From where data/document is obtainable

Dr. Solmaz Maleki Dizaj, Tabriz Faculty of Dentistry

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

It can be in person or by email.

Comments