

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Fabrication and clinical study of the effect of lavender chewing gum on salivary Streptococcus mutans, salivary pH, plaque index, and gingival bleeding

Protocol summary

Study aim

Fabrication and clinical study of the effect of lavender chewing gum on salivary Streptococcus mutans, salivary pH, plaque index, and gingival bleeding

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, with 57 participants. For randomization, sealed envelopes with predefined codes (code A: intervention and code B: control) that will be placed inside the bag will be used. Participants randomly select an envelope. After identifying the code, appropriate treatment is considered. The evaluator and the participant are not aware of any of the treatments.

Settings and conduct

Study of a double-blind, randomized (by random number table), with control and intervention group (lavender gum), on the staff of Tabriz University of Medical Sciences. Consume lavender gum for 2 weeks and then dental plaque and bacterial status of saliva will be checked. The evaluator and participant are not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion: Participants do not have systemic disease, Have acceptable oral hygiene (do not have a clear mass and plaque), Age range 18 to 65 years, People who have an average of 22 teeth, Do not be pregnant or breastfeeding Exclusion: Taking antibiotics or drugs that affect saliva, Use of an oral appliance, Smoking, and alcohol consumption, People with temporomandibular joint problem

Intervention groups

The staff of Tabriz University of Medical Sciences will be studied in two groups, the intervention (Chewing gum containing lavender extract) and the control (Chewing gum without lavender extract). The amount of chewing gum used by each person daily will be six pieces, one after each meal and three pieces during the day for at

least 15 minutes for 14 consecutive days.

Main outcome variables

Plaque index and bleeding gums, number of Streptococcus mutans saliva colonies, saliva pH

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220122053799N1**

Registration date: **2022-03-05, 1400/12/14**

Registration timing: **prospective**

Last update: **2022-03-05, 1400/12/14**

Update count: **0**

Registration date

2022-03-05, 1400/12/14

Registrant information

Name

Fatemeh Safari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3329 1996

Email address

mkoohsoltani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2022-06-04, 1401/03/14

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Fabrication and clinical study of the effect of lavender chewing gum on salivary Streptococcus mutans, salivary pH, plaque index, and gingival bleeding

Public title
Fabrication and evaluation of the effect of lavender gum in the mouth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Participants do not have systemic disease Have acceptable oral hygiene (no clear mass and plaque) Age range 18 to 65 years Do not be pregnant or breastfeeding Having an average of 22 teeth
Exclusion criteria:
 Taking antibiotics or drugs that affect saliva Use oral appliance Smoking and alcohol consumption People with temporomandibular joint problems

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
The study will be conducted randomly among the staff of Tabriz University of Medical Sciences. The method of randomization is simple and its unit is individual. Randomization will be performed in such a way that the first group is identified by code A (intervention) and the second group by code B (control) and will be placed inside sealed envelopes; The envelopes are then placed in a bag and shaken. After returning to the place, people put their hands inside the bag and randomly take out an envelope. After viewing the code, the treatment will be given to the patient. The evaluator and participant are not aware of the type of groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study is two-way blind and the outcome assessor, data analyst, and study participant are not aware of the type of groups. The researcher and outcome assessors are not aware of the randomization

and segmentation of the Chewing gums among the participants and do not intervene. To blind the participants to the taste of chewing gum, the same flavoring is added to both types of chewing gum.

Placebo
Used

Assignment
Parallel

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

No. 47, East 4th Floor, Mehdian Alley, Azari St., Valiasr Intersection, Tabriz Town

City

Tabriz

Province

East Azarbaijan

Postal code

5167616775

Approval date

2022-01-12, 1400/10/22

Ethics committee reference number

IR.TBZMED.REC.1400.1003

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

K02.3

ICD-10 code description

Arrested dental caries

Primary outcomes

1

Description

Gingival bleeding rate

Timepoint

Measure the percentage of plaque index at the beginning of the study (before the intervention) and 14 days after the start of chewing gum.

Method of measurement

Bleeding index using periodontal prop in Salcus at four levels (labial, Lingual and Interproximal)

2

Description

Check the percentage of license plate index

Timepoint

Measure the percentage of plaque index at the beginning of the study (before the intervention) and 14 days after the start of chewing gum.

Method of measurement

Plaque detector tablets

3

Description

Measurement of the number of Streptococcus mutans saliva colonies

Timepoint

Measure the percentage of plaque index at the beginning of the study (before the intervention) and 14 days after the start of chewing gum.

Method of measurement

The patient will be asked to collect saliva in the mouth for one minute and then pour it into a sterile Falcon graduated tube. To determine the number of Streptococcus mutans colonies, they should be sent to the microbiology laboratory and incubated in the specific medium of Mitis salivarius agar at 37 ° for 2 days and Streptococcus mutans were counted.

4

Description

Saliva pH

Timepoint

Measure the percentage of plaque index at the beginning of the study (before the intervention) and 14 days after the start of chewing gum.

Method of measurement

PH meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Chewing lavender gum by extracting the plant by percolation method using 70% ethanol made in Tabriz Medical Research Center. The amount of gum used per person is six pieces of chewing gum daily, one after each meal and three pieces during The day will be for at least 15 minutes for 14 consecutive days.

Category

Treatment - Other

2

Description

Control group: Chewing gum without lavender extract, which is made in Tabriz Medical Research Center. The

amount of chewing gum used by each person daily will be six pieces of chewing gum, one after each meal and three pieces during the day for at least 15 minutes for 14 consecutive days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Dental Hospital

Full name of responsible person

Fatemeh Safari

Street address

Dentistry Faculty of Tabriz, Golgasht Ave, Azadi Blvd

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Web page address

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?

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

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Maryam Kooh Soltani
Position
Assistant Professor of oral and maxillofacial pathology
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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