Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Clinical evaluation of the effect of Hypericum perforatum gum on salivary streptococcus mutans count, salivary pH, plaque index and gingival bleeding

Protocol summary

Study aim

Fabrication and analysis of herbal chewing gum using herringbone, Evaluation of plaque index and gingival bleeding, Measurement of Streptococcus mutans in saliva, Saliva pH measurement

Design

A control group with a randomized double-blind parallel group on 54 volunteers based on a random number table

Settings and conduct

It is in the field of prevention of periodontal disease and caries and will be performed in the School of Dentistry of Tabriz University of Medical Sciences. At the beginning of the study, the amount of Streptococcus mutans in saliva acidity, the plaque index and the gingival bleeding index will be determined and recorded. The daily dose of chewing gum used by each person will be 6 pieces per day, for 14 consecutive days.

Participants/Inclusion and exclusion criteria

Admission requirements: Participants should not have systemic disease, they should have acceptable oral hygiene (no clear tartar and plaque). participants should be between 18 to 65 years old. Conditions for not entering: not cooperating properly, not using the chewing gum, occurrence of disease during the study period, taking antibiotics or drugs that affect saliva, using oral appliance, being pregnant or breastfeeding

Intervention groups

Volunteers are randomly assigned to one of the intervention or control groups, which is chewing the gum without extract of St. John's wort, the study of double-blind intervention will be performed on volunteers for 2 weeks. As a result of this study, the amount of streptococcus mutans bacteria in saliva, O'Leary plaque index, gingival bleeding and saliva pH before and after chewing gum will be calculated in both groups. the data of two groups will also be compared.

Main outcome variables

This study can be useful to reduce oral disease, especially in patients with periodontal disease and caries and people with some degree of depression.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211212053373N1**
Registration date: **2022-01-23, 1400/11/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-23, 1400/11/03**
Update count: **0**

Registration date

2022-01-23, 1400/11/03

Registrant information

Name
Aylin Jamali
Name of organization / entity
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Iran (Islamic Republic of)
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aylin.jli1997@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-19, 1400/10/29

Expected recruitment end date

2022-04-18, 1401/01/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical evaluation of the effect of Hypericum perforatum gum on salivary streptococcus mutans count, salivary pH, plaque index and gingival bleeding

Public title
The effect of the herring gum on the salivary bacteria, the salivary acidity, gingival plaque and bleeding
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Participants should not have systemic disease Participants should have acceptable oral hygiene (they should not have obvious dental plaque) Age range: 18 to 65 years
Exclusion criteria:
Taking antibiotics or drugs that affect saliva Use of oral appliance Lack of proper cooperation People who breastfeed or are pregnant.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization will be done by using a random number table. Random number tables are generated by computers that randomly adjust numbers. These tables are many and have different names; these tables have random numbers in both rows and columns and usually have more than 99 rows and columns. The rows and the columns are arranged in five-digit blocks next to each other and separately to use. Facilitate it. Due to the fact that the study is two-sided, except for the supervisor as the third person in the study, none of the volunteers or students doing the project will be aware of the study person in the control or intervention group and to define information for individuals will be .
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the participants will be provided with the necessary explanations and description of random selection of their presence in the control and intervention group and then they will sign the consent. The participants, the student with the project as a researcher, the clinical supervisor, the initial draft author of the article and the statistical consultant responsible for data analysis are blind and only the supervisor as an outcome assessor knows how to assign individuals to the control and intervention group. To ensure non-disclosure, each candidate will be assigned a code (due to the fact that the study is at the university level there is no safety monitoring committee) .
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
Azadi St., Golgasht St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2021-12-06, 1400/09/15
Ethics committee reference number
IR.TBZMED.REC.1400.878

Health conditions studied

1

Description of health condition studied
Periodontal diseases
ICD-10 code
K05.6
ICD-10 code description
Periodontal disease, unspecified

Primary outcomes

1

Description
Percentage change in plaque index and gingival bleeding before and after chewing gum
Timepoint
Measurements at the beginning of the study and after 14 days of chewing gums

Method of measurement

Bleeding index, using periodontal prop in four levels of the sulcus, will be measured slowly for 30 seconds before and after using the chewing gum in each intervention and control group. Dental Plaque Index (DPI) will be calculated using the O'Leary index.

2

Description

Measurement of streptococcus mutans in saliva

Timepoint

Measurements at the beginning of the study and after 14 days of using chewing gum

Method of measurement

Samples will be sent to the microbiology laboratory to determine the number of Streptococcus mutans colonies, the data of the control group and the intervention group will be analyzed using the Analysis of Covariance (ANCOVA), first in each group separately and then jointly. Saliva collection of these individuals will be done by the unstimulated method and will be cultured in order to count the number of Streptococcus mutans in a specific medium of Mitis salivarius agar at 37 ° C.

3

Description

Saliva pH difference before and after using the vegetable gum

Timepoint

On the day 15 of the experiment

Method of measurement

1 ml of saliva will be applied to the pH meter electrode for four consecutive measurements after 0, 5, 10, 15, 20 minutes of using the chewing gum. The final salivary pH will be recorded as the average of the three measurements. Independent t-test and covariance test will be used after measuring the pH of saliva in the two groups of control and intervention, before and after using chewing gum, with an average of three times.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The plant will be collected from the botanical garden of Tabriz University. After getting the approval of the herbarium of the University of Medical Sciences and obtaining its code, 300 grams of dried flowering branches will be pulverized. Plant extraction will be done by percolation method using 70% ethanol. The phenol and flavonoid levels of the extract will be determined. In the next step, the raw materials for making chewing gum will be prepared as follows. Chewing gum base is an insoluble and ineffective non-nutritious product that is used as an oral support and chewing gum solution (sugar, glucose, poly oils and flavorings). The gum base composition may contain ordinary elastomer solvents to help soften the elastomer base component. The melting process was performed in the containers at about 50-60 ° C on a steam bath and allowed to cool to 15-20 ° C. Liquid glucose of aspartame glycerin and other non-sucrose sweeteners will be added to the required amount after mixing and extracting, and the mass of each piece of gum will be determined. The remaining amount of solid used will be up to 50-20 mg inside the formulation. The gums will be prepared together and the uniformity test and the release rate of the drug or active substance will be measured according to the standard method. The dimensions of the products in the clean glass molds will be set. The next step in the weight uniformity test is to evaluate the mechanical properties of the gum, such as the amount of traction, which is performed using a traction tester in which a piece of gum is fixed between two clamps. In this test, the gum is pulled by a clamp and pulled until it fails or loses its elasticity. Using this process, quantitative measurements of mechanical properties such as performance strength, ultimate tensile strength, and modulus or Young modulus flexibility can be obtained from segmented stress-strain curves. Evaluation of organoleptic properties and release rate of active ingredients will be done in the laboratory. Lemon powder will be added at the end of the formulation to make all participants feel the same taste. The amount of chewing gum used daily by each person 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

Prevention

2

Description

Control group: Chewing gum is an extract of the hypericum plant. Chewing gum base is an insoluble and ineffective non-nutritious product that is used as an oral support and chewing gum solution (sugar, glucose, poly oils and flavorings). The gum base composition may contain ordinary elastomer solvents to help soften the elastomer base component. The melting process was performed in containers at about 50-60 ° C on a steam bath and allowed to cool to 15-20 ° C. Liquid glucose of aspartame glycerin and other non-sucrose sweeteners will be added to the required amount after mixing and extracting and the mass of each piece of gum will be determined. The dimensions of the products will be adjusted in clean glass molds. The next step in the weight uniformity test is to evaluate the mechanical properties of the gum, such as the amount of traction, which is performed using a traction tester in which a piece of gum is fixed between two clamps. In this test, the gum is pulled by a clamp and pulled until it fails or loses its elasticity. Using this process, quantitative measurements of mechanical properties such as performance strength, ultimate tensile strength, and modulus or Young modulus flexibility can be obtained from segmented stress-strain curves. Evaluation of organoleptic properties and release rate of active

ingredients will be done in the laboratory. In order for all participants to feel the same taste, lemon powder will be added at the end of the formulation. The amount of chewing gum used by each person is six pieces of chewing gum daily, one after each meal and three pieces during the day for at least 15 minutes for 14 It will be a consecutive day.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Dentistry, Tabriz University of Medical Sciences

Full name of responsible person
Dr. Maryam Kooh Soltani

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Azadi St., Golgasht St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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Web page address
https://researchvice.tbzmed.ac.ir/

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
Dr. Maryam Kooh Soltani

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Aylin Jamali

Position

Student

Latest degree

A Level or less

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

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

Title and more details about the data/document

Total potential data after non-identification of individuals

When the data will become available and for how long

Access period starts 3 months after the results are published

To whom data/document is available

Includes all people in the academia and the industry

Under which criteria data/document could be used

For the clinical studies and completion and promotion

From where data/document is obtainable

Dr. Maryam Kooh Soltani,mkoohsoltani@yahoo.com

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

Getting the approval of the Research Committee of the University of Medical Sciences and the consent of the project owners

Comments