

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical Evaluation of anti plaque and antimicrobial efficacy of bamboo salt toothpaste by culturing of Streptococcus mutans and Lactobacilli and plaque index evaluation

Protocol summary

Study aim

Clinical Evaluation of anti plaque and antimicrobial efficacy of bamboo salt toothpaste by culturing of Streptococcus mutans and Lactobacilli and plaque index evaluation.

Design

In this third-phase RCT, sample size is calculated to be 26 in each group based on previous studies, which will be increased to 30 to improve the validity of study. participants will be assigned to the case (bamboo salt toothpaste) and control (Crest toothpaste) using random number table.

Settings and conduct

After completing the written informed consent by all participants, the baseline plaque index will be determined using the Turesky index and baseline saliva sampling will be performed. All participants (case group using bamboo salt toothpaste and control group) will be instructed to brush their teeth for two minutes using the Bass technique twice a day for four weeks. Saliva sampling and plaque index determination will be repeated after four weeks of toothpaste use. For saliva sampling, two milliliters of unstimulated saliva will be transferred into microtubes and immediately transferred to the laboratory of microbiology.

Participants/Inclusion and exclusion criteria

Dental students of Shahid Beheshti dental school aged 18-24 years old Inclusion Criteria - Without periodontal pocket depth of more than three millimeters - Without history of smoking and dry mouth - Without using of orthodontic appliances - Without untreated dental caries - Without history of systemic disease - History of routine daily toothbrushing with fluoride-containing toothpastes - Without receiving antibiotic or anti-inflammatory drugs at least one month - Without allergic reaction to the toothpaste

Intervention groups

case group: consumers of bamboo salt toothpaste

control group: consumers of Crest Complete toothpaste

Main outcome variables

Plaque Index , Streptococcus mutans count , Lactobacillus count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210414050964N1**

Registration date: **2021-06-21, 1400/03/31**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-21, 1400/03/31**

Update count: **0**

Registration date

2021-06-21, 1400/03/31

Registrant information

Name

Romina Roodgarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2670 8362

Email address

rominaroodgarian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Evaluation of anti plaque and antimicrobial efficacy of bamboo salt toothpaste by culturing of Streptococcus mutans and Lactobacilli and plaque index evaluation

Public title

Antimicrobial and anti plaque efficacy of herbal toothpaste containing Bamboo salt

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Without periodontal pocket depth of more than three millimeters Without history of smoking and dry mouth Without using of orthodontic appliances Without presence of untreated dental caries Without history of systemic diseases routine daily toothbrushing with fluoride-containing toothpastes Without receiving antibiotic or anti-inflammatory drugs at least one month prior to the study Without allergic reaction to the toothpaste

Exclusion criteria:

Pregnant Lactating women History of using other herbal drugs at least one month prior the study

Age

From **18 years** old to **24 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Assignment The participants by use of random number table were randomly assigned into the control and case groups In this method, at first, in order to read the numbers(e.g. up, down, right, and left), the even numbers are considered for the case group, while the odd numbers are consider for the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Considerg the same mint flavour of the two toothpaste, information labels on all toothpaste tubes will be removed and their packages will be all designed similarly, in order to ensure the blinding of participants to the contents of toothpaste tubes. Colony counting will be also performed by a blind microbiologist (by coding

the saliva samples, A as control group and B as case group)

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

institutional ethics committee of biomedical research of dental science's institue

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Velenjak St.,Shahid Chamran Highway

City

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Postal code

1983963113

Approval date

2020-08-24, 1399/06/03

Ethics committee reference number

IR.SBMU.DRC.REC.1399.033

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

anti plaque and antimicrobial efficacy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

plaque index

Timepoint

At baseline and after four weeks of toothpaste use

Method of measurement

plaque indicator

2**Description**

Lactobacillus

Timepoint

At baseline and after four weeks of toothpaste use

Method of measurement

cultivating and count bacteria

3

Description

Streptococcus mutans

Timepoint

At baseline and after four weeks of toothpaste use

Method of measurement

cultivating and count bacteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The bamboo salt toothpaste (Tiger Herb®, LG, Korea), The Tiger Herb contains Hydrated Silica, Sodium Chloride (Bamboo Salt), Dipotassium Glycyrrhizinate, Sodium Fluoride, Sorbitol Solution (70%), Cellulose Gum, Sodium Saccharin, Sodium Lauryl Sulfate, Sodium Bisulfate, Blue 1 (E142090), Yellow 10 (47005) Flavor, mint extract and Water. All participants will be instructed to brush their teeth with a medium bristled brush (Oral-B, Ireland) by using 1 centimeter toothpaste for two minutes using the Bass technique twice a day (after breakfast and before bedtime) for four weeks. They will be also instructed to use non-fluoridated dental floss (Oral B, Ireland) every night before going to bed, and refrain from using other fluoride-containing products. Saliva sampling plaque index will be performed at baseline and after four weeks of toothpaste use

Category

Prevention

2

Description

Control group: Crest® Complete toothpaste (Procter & Gamble Plaza, Cincinnati, OH 45202, United States) The Crest Complete toothpaste contains Aqua, Sorbitol, Hydrated Silica, Sodium Lauryl Sulfate, Cellulose Gum, mint extract, Aroma, Zinc Citrate, Chondrus Crispus Powder, Sodium Fluoride (1450 ppm), Sodium Saccharin, Hydroxyl Ethylcellulose, CI 77891, Sodium Citrate, Stannous Chloride, Silica, Glycerin and CI 74160. All participants will be instructed to brush their teeth with a medium bristled brush (Oral-B, Ireland) by using 1 centimeter toothpaste for two minutes using the Bass technique twice a day (after breakfast and before bedtime) for four weeks. They will be also instructed to use non-fluoridated dental floss (Oral B, Ireland) every night before going to bed, and refrain from using other fluoride-containing products. Saliva sampling plaque index will be performed at baseline and after four weeks of toothpaste use

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti dental school

Full name of responsible person

Mina Biria

Street address

Velenjak St., Shahid Chamran Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Romina Roodgarian

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mina Bira

Position

Assistant Prof., Department of Pediatric Dentistry,
School of Dentistry, Shahid Beheshti University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Romina Roodgarian

Position

Resident of pediatric dentistry

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mina Biria

Position

Assistant Prof., Department of Pediatric Dentistry,
School of Dentistry, Shahid Beheshti University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

participants Privacy

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available