

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparsion of the antimicrobial effect of two toothpastes on salivary streptococcus mutans and lactobacillus and candida albicans of plaque in children aged 4 to 6 years with Early Childhood Caries

Protocol summary

Candida albicans colonies cultured in culture medium

Study aim

Comparsion of antimicrobial effect of aloe vera containing toothpaste and fluoride toothpaste on the amount of salivary Streptococcus mutans and Lactobacillus and Candida albicans of plaque in children 4 to 6 years old with ECC

Design

This study is a clinical trial with a control group on 26 patients, with cross-over design and double-blind, which is randomized by simple method.

Settings and conduct

The study is performed at the School of Dentistry, Shahid Sadoughi University of Medical Sciences, Yazd, Iran. Saliva and plaque sampling is done before using the first type of toothpaste in each group and one month after its consumption. After a waiting period of 2 weeks, two groups will use opposite toothpastes. Similar to the first period, sampling is done. Patients, microbiologists and statistics analyst are not aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Children 4 to 6 years old with ECC who have 2 to 3 decayed teeth and their parents are willing to participate in the study and who are positive or completely positive according to Frankel behavior scale. Children without systemic disease who have no intraoral pathology. Children who have not had a history of receiving professional topical fluoride as well as antibiotics in the past 3 months or during treatment.

Intervention groups

In order to evaluate the antimicrobial effect of two toothpastes, the samples were randomly assigned to receive aloe vera toothpaste at one stage in the study group and then fluoridated toothpaste at another stage in the control group.

Main outcome variables

Number of Streptococcus mutans; Lactobacillus and

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191004044977N2**

Registration date: **2020-12-18, 1399/09/28**

Registration timing: **prospective**

Last update: **2020-12-18, 1399/09/28**

Update count: **0**

Registration date

2020-12-18, 1399/09/28

Registrant information

Name

Maedeh Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the antimicrobial effect of two toothpastes on salivary streptococcus mutans and lactobacillus and candida albicans of plaque in children aged 4 to 6 years with Early Childhood Caries

Public title

Antimicrobial effect of two toothpastes in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children aged 4 to 6 years who have 2 to 3 decayed teeth Children without systemic disease Not receiving professional topical fluoride in the last 3 months Absence of any intraoral pathology Children who are positive or completely positive according to Frankel Behavior scale Consent of parents and patients to participate in the study

Exclusion criteria:

Children who need emergency dental treatment Children undergoing orthodontic treatment or with intraoral prostheses Take antibiotics 3 months before treatment or during treatment

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **26**

More than 1 sample in each individual

Number of samples in each individual: **4**

According to receiving a sample from the patient before the delivery of the first type of toothpaste and one month after its consumption and also receiving the sample before the delivery of the second type of toothpaste and one month after its consumption, each patient has four samples.

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple and individual using a list of random numbers that includes two groups A and B. In group A, patients are given aloe vera toothpaste in the first phase and in group B, in the first phase, fluoride toothpaste is given to patients. The listed numbers are written on the same paper and placed in the same envelope. The envelopes are opaque and do not have any mark or writing. All 26 envelopes are placed in a box, and after determining the adequacy of the sample to enter the study and obtain informed consent, the patient is asked to choose one of the envelopes in the box. The envelope is opened, the patient number and the

type of intervention in the first phase are determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the uniform coverage of the toothpaste tubes, the patient is unaware of which treatment group she/he is in. Also, the microbiologist is unaware of which group the samples belong to. The statistics analyst is not aware of type of intervention for each patient.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Sadoughi University of Medical Sciences **برد**

Street address

Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square

City

Yazd

Province

Yazd

Postal code

89148-15669

Approval date

2020-07-28, 1399/05/07

Ethics committee reference number

IR.SSU.REC.1399.100

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

Dental caries

ICD-10 code

K02.9

ICD-10 code description

Dental caries, unspecified

Primary outcomes**1****Description**

Salivary Streptococcus mutans

Timepoint

At the beginning of the study and 30 days later

Method of measurement

Counting the number of Streptococcus mutans colonies

in MSA culture medium 2 Description Salivary lactobacillus Timepoint At the beginning of the study and 30 days later Method of measurement Counting the number of lactobacillus colonies in MRS culture medium	Yazd Postal code 8914815669 Phone +98 35 3621 4257 Email mrezaei2024@gmail.com Sponsors / Funding sources
3 Description Candida Albicans plaque Timepoint At the beginning of the study and 30 days later Method of measurement Counting the number of Candida albicans colonies in Sabouraud dextrose agar culture medium Secondary outcomes empty Intervention groups	1 Sponsor Name of organization / entity Yazd University of Medical Sciences Full name of responsible person Masoud Mirzae Street address Bahonar Square , Central Building of University of Medical Sciences City Yazd Province Yazd Postal code 8916978477 Phone +98 35 3724 0171 Email masoud_mirzae@hotmail.com Grant name Grant code / Reference number Is the source of funding the same sponsor organization/entity? No Title of funding source Yazd 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
1 Description Intervention group: Use aloe vera toothpaste (Forever Living Product, Scottsdale, AZ, USA) for thirty days. Then the wash out period for 2 weeks and displacement of control and case groups . Category Treatment - Other 2 Description Control group: Use fluoride toothpaste (2080; Aekyung Industrial, Seol, Korea) for thirty days. Then the wash out period for 2 weeks and displacement of control and case groups . Category Treatment - Other Recruitment centers	Person responsible for general inquiries Contact Name of organization / entity Yazd University of Medical Sciences Full name of responsible person Maedeh Rezaei Position Resident Latest degree Medical doctor Other areas of specialty/work Dentistry
1 Recruitment center Name of recruitment center Dentistry Faculty of Shahid Sadoughi Full name of responsible person Maedeh Rezaei Street address Dahe fajr Ave, Immam Reza Square, Shahid Sadoughi University City Yazd Province	

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Maedeh Rezaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Undetectable information will be released, including age, sex and number of decayed teeth. The results of the study, including the number of bacterial and fungal colonies, will also be published.

When the data will become available and for how long

Starting 9 months after publication

To whom data/document is available

The data are only available for people working in academic institutions.

Under which criteria data/document could be used

Use of this data is permitted for systematic review and meta-analysis . Similar clinical trials can also use to criticize the present study and its results in their discussion.

From where data/document is obtainable

Send an email to 1 : mrezaei2024@gmail.com 2: zbahrololoom@yahoo.com

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

After the request via one of the two methods listed above, if the request matches the sharing information mentioned before, this information will be available to the applicant within one month.

Comments