Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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 Chilhdood Caries

Protocol summary

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 Candida albicans colonies cultured in culture medium

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)

Phone

+98 31 5351 6111

Email address

mrezaei2024@gmail.com

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
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 Chilhdood 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 یزد

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

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

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

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
Yazd
Postal code
8914815669
Phone
+98 35 3621 4257
Email
mrezaei2024@gmail.com

Sponsors / Funding sources

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

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

Street address
Dentistry Faculty of Shahid Sadoughi University of Medical Sciences, Imam Reza Square, Dahe fajr Ave.
City
Yazd
Province
Yazd
Postal code
8914815669
Phone
+98 35 3621 4257
Email
mrezaei2024@gmail.com

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
Dentistry
Street address
Dentistry Faculty of Shahid Sadoughi University of Medical Sciences, Imam Reza Square, Dahe fajr Ave.
City
Yazd
Province
Yazd
Postal code
8914815669
Phone
+98 35 3621 4257
Email
mrezaei2024@gmail.com

Person responsible for updating data

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
Street address
Dentistry Faculty of Shahid Sadoughi University of Medical Sciences, Imam Reza Square, Dahe fajr Ave.
City
Yazd
Province
Yazd
Postal code
8914815669
Phone
+98 35 3621 4257
Email
mrezaei2024@gmail.com

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 criticiza 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