Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the amount of salivary pH changes following the use of arginine mouthwash: a randomized clinical trial

Protocol summary

Study aim

Investigating and comparing the amount of saliva pH changes following the use of 0.5 and 1% arginine mouthwash as a clinical trial

Design

A clinical trial with two parallel groups, without a control group, double-blind, randomized, phase 1 on 24 patients. Sealed envelopes will be used for randomization.

Settings and conduct

Twenty-four eligible children will enter the study. 0.5 and 1% arginine mouthwashes will be prepared and labelled A on the 0.5% mouthwashes and B on the 1% mouthwashes. On 12 cards, tag A, and on the other 12 cards, tag B is written and will place inside the sealed envelopes. On the test day, the responsible personnel will randomly open an envelope and use the mouthwash specified for the participant. At the beginning of the experiment and before using the mouthwashes, 1 ml of unstimulated saliva of the participants will be collected in an upright position. Then the participants will gargle 10 ml of the indicated mouthwash for 1 minute. Then 1 ml of their unstimulated saliva will be collected 5, 10, 15, and 20 minutes after using the mouthwash in an upright position. Then the pH of the collected saliva samples will be measured with a digital pH meter.

Participants/Inclusion and exclusion criteria

Twenty-four 6-12 years-old children who are healthy without systemic disease and with intact teeth free from caries and periodontal disease, who have not taken any antibiotics in the last four weeks, will be included in the study.

Intervention groups

Group A: 0.5% arginine mouthwash,Group B: 1% arginine mouthwash

Main outcome variables

Saliva pH

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230728058947N1**
Registration date: **2023-08-09, 1402/05/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-09, 1402/05/18**
Update count: **0**

Registration date

2023-08-09, 1402/05/18

Registrant information

Name

Mehrnaz Mahmoodabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 4422 9142

Email address

mahmoodabadimehrnaz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2023-11-11, 1402/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the amount of salivary pH changes following the use of arginine mouthwash: a randomized clinical trial

Public title
Investigating the effect of arginine mouthwash on salivary pH
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy children aged 6 to 12 without systemic disease Children with intact teeth, that are free from caries and enamel lesions and periodontal disease Children who have not taken any antibiotics in the last 4 weeks
Exclusion criteria:
Children with systemic diseases Children with decayed teeth or structural problems in the enamel Children who have taken antibiotics in the last four weeks
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **12**
Randomization (investigator's opinion)
Randomized
Randomization description
A sealed envelope was used for randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants, the personnel responsible for providing mouthwash to the participants, the saliva sample collector, and the statistics expert were unaware of the percentage of mouthwash on the day of the experiment, and the groups of mouthwash named A and B were provided to them.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Medical Research, Faculty of Dentistry, Shahid Beheshti University of Medical Sc
Street address
Building No. 2, Second Floor,Shahid Shahriari Square, Student Blvd., Shahid Arabi Street, Shahid Beheshti University of Medical Sciences Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
19395-4631
Approval date
2022-12-10, 1401/09/19
Ethics committee reference number
IR.SBMU.DRC.REC.1401.076

Health conditions studied

1

Description of health condition studied
saliva pH
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Saliva pH
Timepoint
Before using mouthwash, 5, 10, 15 and 20 minutes after using mouthwash
Method of measurement
Using digital pH meter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1% arginine mouthwash
Category
Prevention

2

Description
Intervention group: 0.5% arginine mouthwash
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Pediatrics, School of Dentistry, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mehrnaz Mahmoodabadi

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Building No. 2, Second Floor,Shahid Shahriari Square, Student Blvd., Shahid Arabi Street, Shahid Beheshti University of Medical Sciences Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fahimeh Kooshki

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Building No. 2, Second Floor,Shahid Shahriari Square, Student Blvd., Shahid Arabi Street, Shahid Beheshti University of Medical Sciences Tehran, Iran.

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sec.bms@acecr.ac.ir

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
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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mehrnaz Mahmoodabadi

Position
pediatric dentistry resident

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Latest degree
Medical doctor

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
Not applicable
Data Dictionary
Not applicable