

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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

**Street address**

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+98 21 2243 9872

**Email**

Mahmoodabadimehrnaz@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Fahimeh Kooshki

**Street address**

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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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mehrnaz Mahmoodabadi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

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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