Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

evaluation of the effect of daily usage of postbiotic toothpaste on salivary IgA levels in 6- to 12-year-old children: a triple-blind randomized controlled trial

Protocol summary

Study aim

Determining the effect of daily use of post-biotic toothpaste on salivary IgA in children 6 to 12 years old

Design

Institutional-based, parallel groups, triple-blind, randomized clinical trial. Assignment of patients to study groups will be done using the random block method and using 6 blocks.

Settings and conduct

The research site will be the School of Dentistry of the Ahvaz Jundshapur University of Medical Sciences. Sampling will be performed by the non-probability method. Outcomes are measured before the intervention. Participants will be randomly divided into intervention and control groups and after the intervention, the outcomes will be measured again. In this study, participants, the person evaluating the results and analyzer of the data will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: systemically healthy 6- to 12-year-old children with a mixed dental system Exclusion criteria: the presence of inflammatory disease and use of antibiotics and probiotic products

Intervention groups

Intervention group: Children in this group brush their teeth twice a day for 30 days, using postbiotic toothpaste. Control group: Children in this group brush their teeth twice a day for 30 days, using toothpaste similar to the intervention group. The only difference between the toothpaste used by this group is the lack of postbiotic.

Main outcome variables

Salivary IgA level measured by ELISA kit; Saliva pH measured by pH indicator strips

General information

Reason for update

In the intervention groups section, the name of the microorganism that will be used in the toothpaste was mistakenly written wrong.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191016045128N2**
Registration date: **2022-03-07, 1400/12/16**
Registration timing: **prospective**

Last update: **2025-01-17, 1403/10/28**
Update count: **2**

Registration date

2022-03-07, 1400/12/16

Registrant information

Name

Samaneh Khanehmasjedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3338 9516

Email address

khanehmasjedi.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

2023-05-01, 1402/02/11

Actual recruitment end date

2023-08-20, 1402/05/29

Trial completion date

2023-09-20, 1402/06/29

Scientific title

evaluation of the effect of daily usage of postbiotic toothpaste on salivary IgA levels in 6- to 12-year-old children: a triple-blind randomized controlled trial

Public title

Postbiotics and salivary IgA

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

6- to 12-year-old children In mixed dentition No systemic disease

Exclusion criteria:

Any presence of inflammatory diseases Usage of antibiotics or probiotics within the 2 weeks before start of the study or through it

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients to study groups will be done using random block method and using 6 blocks.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participants, the person evaluating the result of the intervention, and data analyzer have no information regarding the type of the participants' treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Deputy of research and technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2022-03-05, 1400/12/14

Ethics committee reference number

IR.AJUMS.REC.1400.676

Health conditions studied

1

Description of health condition studied

salivary levels of IgA and pH

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Salivary IgA level

Timepoint

before intervention and 30 days after intervention

Method of measurement

Saliva collection and IgA measurement by ELISA kit

Secondary outcomes

1

Description

Salivary pH

Timepoint

before intervention and 30 days after intervention

Method of measurement

pH indicator strips

Intervention groups

1

Description

Intervention group: Children in this group brush their teeth twice a day for 30 days, using toothpaste containing post-biotic Bifidobacterium animalis subsp. animalis with a concentration of 2*10^ 9.

Category

Prevention

2

Description
Control group: Children in this group brush their teeth twice a day for 30 days, using toothpaste similar to the intervention group. The only difference between the toothpaste used by this group is the lack of post-biotic.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of pediatric dentistry, School of dentistry

Full name of responsible person
Leila Basir

Street address
School of dentistry, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3320 5169

Email
dental_research@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mehrnoush Zaker-kish

Street address
1st floor, School of public health, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8392

Email
jitdrc@yahoo.com

Grant name

Grant code / Reference number
0054

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Samaneh Khanehmasjedi

Position
research assistant

Latest degree
Bachelor

Other areas of specialty/work
Dentistry

Street address
Unit 2, No 65, West Mihan street, Chamran avenue, Kianpars

City
Ahvaz

Province
Khouzestan

Postal code
6155814885

Phone
+98 61 3338 9516

Fax

Email
masjedi.samaneh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Samaneh Khanehmasjedi

Position
research assistant

Latest degree
Bachelor

Other areas of specialty/work
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Street address
Unit 2, No 65, West Mihan street, Chamran avenue, Kianpars

City
Ahvaz

Province
Khouzestan

Postal code
6155814885
Phone
+98 61 3338 9516
Fax
Email
masjedi.samaneh@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Samaneh Khanehmasjedi
Position
research assistant
Latest degree
Bachelor
Other areas of specialty/work
Dentistry
Street address
Unit 2, No 65, West Mihan street, Chamran avenue, Kianpars
City
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Province
Khouzestan
Postal code
6155814885
Phone
+98 61 3338 9516
Fax
Email
masjedi.samaneh@yahoo.com

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
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available