

# The effect of probiotic and fluoride mouthwashes on dental plaque

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<b>Registration date</b> 09/08/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/08/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Tooth decay (dental caries) is the most common health problem affecting 60–90% of children and adolescents. Tooth decay is damage to a tooth that can happen when decay-causing bacteria in your mouth (called dental plaque) make acids that attack the tooth's surface or enamel. Researchers have shown that only using a mechanical technique to remove dental plaque is ineffective, therefore mouthwashes were taken into consideration. To reduce the disadvantages associated with chemical antimicrobial agents (Fluoride), this study investigates the use of a probiotic therapy as an alternative mouthwash for dental use on plaque accumulation in children after 7, 14 and 30 days of use.

### Who can participate?

Children aged between 8-10 years old

### What does the study involve?

The study aims to compare the effectiveness of nonchemical mouthwashes (Probiotic) with chemical mouthwashes (Fluoride). Participants will be randomly divided into two groups to wash their mouth with probiotics mouth wash or fluoride and then the quantity of plaque in the mouth will be measured after 7, 14 and 30 days of use.

### What are the possible benefits and risks of participating??

No benefits and risks of participation were provided at time of registration

### Where is the study run from?

Dar Al-Rahma for orphan children in Damascus (Syria)

### When is the study starting and how long is it expected to run for?

May 2018 to March 2020

### Who is funding the study?

Damascus University (Syria)

Who is the main contact?  
Dr Enas Marwan AlHallak (Syria)  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
3514

## Study information

**Scientific Title**  
The evaluation of the effectiveness of probiotic mouthwashes in reducing dental plaque in primary and permanent teeth: Randomized clinical trial

**Study objectives**  
Using probiotic mouthwashes is more effective than fluoride mouthwashes in reducing dental plaque

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 27/8/2018, Scientific research and postgraduate studies board, (Faculty of Dentistry, Damascus University, Syria; +96390404849; osama.aljabban@gmail.com), ref: none available

### **Study design**

Interventional triple-blinded randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Prevention

### **Participant information sheet**

No participant information sheet available

### **Health condition(s) or problem(s) studied**

Dental plaque

### **Interventions**

The present study is a randomized controlled trial including 30 healthy children (12 male, 18 female) from Dar Al-Rahma for orphan children in Damascus, Syrian Arab Republic assigned into two parallel groups (A, B).

Randomization: Simple random sampling will be employed by the random number table method and every group has randomly used one mouthwash by lottery method. The random allocation sequence was created by one of the authors using the random number table method. The random allocation sequence will be hidden from the main investigator. The major investigator will register the study subjects and evaluate the study index.

Blinding: The blinding will be controlled by a third person (dentist) who divides the mouthwashes into simple plastic bottles of the same specific size for Group A and Group B. All participants and the researcher will not know the contents of the bottles. The third person is unblinded to the contents after the end of the study. The statistician will also be blinded therefore, this was a triple-blind study.

All of the children will be taught to brush their teeth by the circulation method within a week of starting the study, and it will be confirmed that they master the method. Identical new brushes and non-fluoride toothpaste will be distributed to all of them. In addition, scaling and polishing will be done before starting the study. When the study starts, group (A) will use (10) ml of probiotic mouthwashes (PROBIOCLEAN, United States), and group (B) will use (10) ml of fluoride mouthwashes (Colgate, United States) for 60 seconds. The use of the mouthwash by all the children will be monitored by the main investigator.

**Intervention Type**

Other

**Primary outcome measure**

Plaque accumulation measured using the Turesky Modified Quigley – Hein (TMQH) plaque index on days 7, 14 and 30

**Secondary outcome measures**

There are no secondary outcome measures

**Overall study start date**

01/05/2018

**Completion date**

01/03/2020

**Eligibility****Key inclusion criteria**

1. Aged between 8-10 years old
2. Systemically healthy children with good oral health
3. Eruption of permanent incisor and first permanent molar
4. Presence of primary second molar, no decay on the buccal surface of examined teeth
5. Children who are able to cooperate with the study

**Participant type(s)**

Healthy volunteer

**Age group**

Child

**Lower age limit**

8 Years

**Upper age limit**

10 Years

**Sex**

Both

**Target number of participants**

30

**Total final enrolment**

30

**Key exclusion criteria**

1. Children with physical, mental, or physical disabilities
2. Use of antibiotics, anti-inflammatories, or oral rinses at least four weeks before this study

3. Undergoing a preventive oral program during the past three months before the start of the tests

4. Sensitivity to one of the research materials

**Date of first enrolment**

29/01/2020

**Date of final enrolment**

01/03/2020

## **Locations**

**Countries of recruitment**

Syria

**Study participating centre**

Dar Al Rahme for orphan children in Syria

Rekn Alden

Damascus

Syria

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## **Sponsor information**

**Organisation**

Damascus University

**Sponsor details**

Almazzeah

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**Sponsor type**

University/education

**Website**

<http://www.damascusuniversity.edu.sy>

**ROR**

<https://ror.org/03m098d13>

# Funder(s)

## Funder type

University/education

## Funder Name

Damascus University

## Alternative Name(s)

University of Damascus, , DU

## Funding Body Type

Government organisation

## Funding Body Subtype

Universities (academic only)

## Location

Syria

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

31/12/2022

## Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study will be published as a supplement to the subsequent results publication

## IPD sharing plan summary

Published as a supplement to the results publication