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The effect of probiotic and fluoride mouthwashes on dental plaque

Submission date 24/07/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/08/2022	**Overall study status** Completed	
Last Edited 09/08/2022	**Condition category** Oral Health	

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 form?
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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Interventional triple-blinded randomized controlled trial

Study type(s)
Prevention

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

Key secondary outcome(s)
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
10 Years

Sex
All

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

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

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