

# Probiotics for gum health during treatment with braces

<b>Submission date</b> 04/09/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/04/2020	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

The use of orthodontic appliances (braces) increases biofilm (bacteria) retention and may lead to periodontal (gum) deterioration. Probiotics have been suggested to be beneficial in preventing or treating gingival (gum) inflammation. The aim of this study is to assess the inflammatory changes in the periodontium (gums) of orthodontic patients taking probiotics compared to usual oral hygiene. Secondary aims include assessing plaque, side effects, patient-reported outcomes and salivary microbiome (bacteria).

### Who can participate?

Orthodontic patients aged under 18

### What does the study involve?

Participants are randomly allocated to one of two groups. Group 1 consume probiotic tablets together with regular oral hygiene, while individuals in Group 2 do not receive the probiotic supplements. Assessments take place at the start of the study and after 3 months, assessing plaque, gingivitis (gum inflammation), gingival bleeding, potential side effects and patient-reported outcomes. Saliva samples are collected for salivary microbiome tests.

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

Not provided at time of registration

### Where is the study run from?

Mohammed Bin Rashid University of Medicine and Health Sciences (United Arab Emirates)

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

February 2018 to December 2020

### Who is funding the study?

Mohammed Bin Rashid University of Medicine and Health Sciences (United Arab Emirates)

### Who is the main contact?

Dr Eleftherios Kaklamanos

# Contact information

## Type(s)

Scientific

## Contact name

Dr Eleftherios Kaklamanos

## ORCID ID

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MBRU-IRB-2018-015

# Study information

## Scientific Title

A single-centre investigator-blinded randomized parallel-group study to investigate the effect of probiotic strains *Streptococcus salivarius* M18 and *Lactobacillus acidophilus* on gingival health of paediatric patients undergoing treatment with fixed orthodontic appliances

## Study hypothesis

Gingival bleeding on probing is less in orthodontic patients consuming probiotics in addition to regular oral hygiene, compared to patients practicing daily home oral hygiene alone.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Mohammed Bin Rashid University of Medicine and Health Sciences Institutional Review Board  
Date of approval: 04 June 2018  
Reference number: MBRU-IRB-2018-015

## Study design

Single-center single-blind (to clinical and laboratory examiner) parallel-group randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised parallel trial

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

Other

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

Prevention

### **Participant information sheet**

#### **Condition**

Gingivitis, malocclusion treatment

#### **Interventions**

Subjects will be randomized into 2 groups with the aid of a computer program:

Intervention group: Probiotic tablet + Usual home oral hygiene [according to manufacturer instructions, the participants will chew two tablets once daily for 3 months]

No Intervention group: Usual home oral hygiene

Data recordings of all patients will take place at baseline and 3 months [end of study] by previously calibrated examiner blinded for the group assignment, assessing plaque, gingivitis, gingival bleeding, potential adverse effects and patient-reported outcomes. Moreover, at baseline and 3-month examinations [end of study], whole saliva samples will be collected for salivary microbiome determination.

#### **Intervention Type**

Supplement

#### **Primary outcome measure**

Gingival bleeding on probing: percentage of the buccal mesial, midline and distal sites from second premolar to second premolar which bleed upon probing, using the criteria for bleeding of the Gingival Index (Löe and Silness, 1963) at baseline and 3 months

#### **Secondary outcome measures**

Measured at baseline and 3 months:

1. Gingival Index assessed on the buccal surfaces from second premolar to second premolar (Löe and Silness, 1963)
2. Plaque Index modified (Clerehugh et al., 1998)
3. Potential adverse effects: inspection of the hard and soft oral cavity tissues and self-reported
4. Patient-reported outcomes (adapted from Herrera et al., 2017)

#### **Overall study start date**

01/02/2018

## **Overall study end date**

31/12/2020

# **Eligibility**

## **Participant inclusion criteria**

1. Healthy individuals, aged under 18 years, planned for simultaneous full arch upper and lower fixed labial orthodontic appliance therapy from second premolar to second premolar
2. In good general health
3. Have a dental history that includes brushing at least once a day
4. Willing and able to comply with the trial regime
5. Normal anatomical periodontal attachment
6. Gingival bleeding on probing on at least 30% of the buccal mesial, midline and distal sites of the teeth examined using the criteria for bleeding of the Gingival Index (Löe and Silness, 1963).

## **Participant type(s)**

Patient

## **Age group**

Child

## **Upper age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

50 (allowing for dropouts)

## **Participant exclusion criteria**

1. Inability to make informed consent
2. Allergies, sensitivities or food intolerance
3. Presence of any congenital syndromes of the head and neck
4. Medical contraindications such as heart condition, immunocompromised state or diseases necessitating antibiotic cover prior to procedures, use of immunosuppressants,
5. History of surgery within the past year or planned within the next 90 days
6. Severe nausea, fever, vomiting, bloody diarrhea or severe abdominal pain within the past one month
7. Presence of special physical or mental needs that would compromise manual dexterity
8. Chronic use of medications of any kind, probiotics or food supplements of any kind
9. Use of antibiotics, anti-inflammatory, steroids or hormones within one month from the start of the study.
10. Oral prophylaxis within one month from the start of the study.
11. Use of antibacterial mouthrinses or toothpastes with supplementary antibacterial agents.
12. Poor compliance with oral hygiene regimens
13. Poor periodontal health such as presence of supragingival calculus, subgingival calculus or periodontal pocketing

14. Extensive dental restorations or uncontrolled caries activity

15. Pregnancy, smokers

16. Planned use of premolar bands

**Recruitment start date**

15/09/2019

**Recruitment end date**

30/03/2020

## **Locations**

**Countries of recruitment**

United Arab Emirates

**Study participating centre**

**Mohammed Bin Rashid University of Medicine and Health Sciences**

Building 14, Dubai Healthcare City

PO Box 505055

Dubai

United Arab Emirates

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## **Sponsor information**

**Organisation**

Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences

**Sponsor details**

Building 34, Dubai Healthcare City

Dubai

United Arab Emirates

PO Box 505055

**Sponsor type**

University/education

**Website**

<https://www.mbruniversity.ac.ae>

**ROR**

<https://ror.org/05g48k331>

# Funder(s)

## Funder type

University/education

## Funder Name

Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences

# Results and Publications

## Publication and dissemination plan

Additional study documents will be available upon request. Presentations in congresses and publication in peer-reviewed articles.

## Intention to publish date

31/07/2021

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	08/09/2019	01/11/2019	Yes	No