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Probiotics for gum health during treatment with braces

Submission date	Recruitment status	[X] Prospectively registered
04/09/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/04/2019	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/04/2020	Oral Health	[_] Record updated in last year

Plain English summary of protocol

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

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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 objectives
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

Health condition(s) or problem(s) studied
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

Completion date
31/12/2020

Eligibility

Key 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)

Key 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, immucompromised 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

Date of first enrolment
15/09/2019

Date of final enrolment
30/03/2020

Locations

Countries of recruitment
United Arab Emirates

Study participating centre
Mohammed Bin Rashid University of Medicine and Health Sciences
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Sponsor information

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

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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?
Protocol article	protocol	08/09/2019	01/11/2019	Yes	No