ISRCTN13794257 https://doi.org/10.1186/ISRCTN13794257

Does laban with probiotics effect the acidity of saliva in individuals with braces?

Submission date
28/05/2024

Recruitment status
No longer recruiting

Registration date
30/05/2024

Overall study status
Completed

Last Edited
30/05/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to investigate the effect of laban containing probiotics on the acidity of saliva in people who have fixed (glued on) braces on their teeth.
When individuals get braces, this leads to some changes in the mouth, such as the degree of acidity of the saliva in your mouth. Increased acid values in combination with difficulty in cleaning teeth with braces can lead to unsightly enamel demineralization, and in severe cases cavities in the teeth. This is an irreversible process. Laban with probiotics has the potential of normalising the acidity in the mouth, thus reducing the effects of demineralization and cavities.

Who can participate?
Anyone with fixed braces attending the Taibah University dental clinics is welcome to participate.

What does the study involve?
The study involves attending to the dental clinic and you will be asked to either rinse with the laban with probiotics, the laban without probiotics or you will not be asked to rinse with anything. Which of these three categories you will recieve will depend on chance. Also, if you do get to rince, neither the dentist caring for you or yourself will know which laban you are rinsing with. This is important for the integrety of the study.
Then the dentist will do a few measurements:
1. They will dry your lower lip and observe when it gets wet again
2. They will ask you to chew on a piece of tasteless wax gum and spit in a little cup
3. Then they will use the saliva in the cup to measure the amount of saliva in the cup as well as the acidity using two different types of strips.
You will be asked to do this 4 times with adequate rest in between.

What are the possible benefits and risks of participating?
There is no pain or discomfort from participating in the study, and you will be serving the community by participating. There is minimum risk to participating in the study. If you are allergic or intolerent to milk, it is important to let us know, and in this case unfortunately you won't be able to participate in the study for your own safety.

Where is the study run from?
Taibah University College of Dentistry (Saudi Arabia)

When is the study starting and how long is it expected to run for?
January 2024 to February 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Safa Jambi
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
TUCDREC/040224/SJambi

Study information

Scientific Title
The effect of probiotic reinforced laban on saliva PH in patients with fixed orthodontic appliances: A three-arm controlled trial

Acronym
PRL SaPHiOr

Study objectives
There is no difference in saliva PH levels in patients with fixed orthodontic appliances who rinse with probiotic-reinforced laban, those who rinse with regular laban, and those who do not rinse.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/02/2024, Taibah University College of Dentistry Research Ethics Committee (TUCD-REC) (Prince Abdulmajeed Ibn Abdulaziz road, Bani Muawiyah, Medinah, 42313, Saudi Arabia; +966 148618888, 77439; tucdrec@taibahu.edu.sa), ref: TUCDREC/040224/SJambi

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Prevention, Efficacy

Participant information sheet
https://docs.google.com/forms/d/e
/1FAIpQLSd6jGzNWuHpLAHFktBSYHV3ZNSOOjswkjJi6iDjMjTHEMaPvg/viewform?pli=1

Health condition(s) or problem(s) studied
Prevention of enamel demineralization and caries in patients with fixed orthodontic appliances.

Interventions
This is a randomized controlled trial investigating the effect of probiotic reinforced laban in comparison to laban not reinforced with probitics and a control group with no treatment. Laban is a yoghurt drink commonly consumed in Saudia Arabia, when it is reinforced with probiotics this may improve salivary PH thus reducing enamel demineralization and caries. Participants will be allocated to one of the three arms by random allocation. The allocation sequence will be generated by an independent researcher. Allocation concealment will be through central randomization; the investigators collecting the data on clinic will contact a central methods center by phone immediately before administering the intervention. Patients will contact a central randomisation site and the interventions administered in the dental clinics. Immediately before the start of the research clinic, an independent researcher will prepare the two interventions (probiotic reinforced and not reinforced laban) in identical plastic cups with plastic covers, these will be coded and labelled to blind the patients, investigators and data collectors.

Decoding will only occur after final analysis of the data. The amount of laban prepared in each cup is 30 ml. Trial participants will be asked to take as much as is comfortable for them and asked to rinse their mouth with it without swallowing, and then spit it out in the dental chair spitoon. Then the salivary outcomes will be measured.

Intervention Type
Other

Primary outcome measure
Saliva PH will be measured using PH test strips which is part of the Saliva-Check Buffer kit from GC company at baseline, 15, 30, 60 min.

Secondary outcome measures
1. Unstimulated saliva measured by visual inspection of the lower lip mucosa after drying with a cotton roll at baseline, 15, 30, 60 min
2. Stimulated saliva measured by asking the patient to chew a wax gum pieces and spit in a collection cup at baseline, 15, 30, 60 min
3. Buferring capacity measured by buffer test strips at baseline, 15, 30, 60 min

Overall study start date
07/01/2024

Completion date
28/02/2025

Eligibility

Key inclusion criteria
Patients with fixed orthodontic appliances visiting Taibah University Dental College, Orthodontic department.

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
78

Key exclusion criteria
1. Patients who have a known allergy to dairy products or lactose intolerance
2. Patients who never consumed dairy products before
3. History of antimicrobial agents within the past 4 weeks
4. Patient with systematic diseases or taking drugs that may effect salivary pH
5. Patients with recent orthognathic surgery

Date of first enrolment
20/04/2024

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Taibah University Dental Hospital
Janadah bin Umayyah Road
Madinah
Saudi Arabia
42353

Sponsor information

Organisation
Taibah University

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Sponsor type
University/education

Website
https://www.taibahu.edu.sa/Pages/AR/Home.aspx

ROR
https://ror.org/01xv1nn60

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal

Intention to publish date
20/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Safa Jambi, drsjanbi@gmail.com

IPD sharing plan summary
Available on request