ISRCTN14397728 https://doi.org/10.1186/ISRCTN14397728

The use of ChloroStay mouthwash for better dental care during brace treatment

Submission date
22/10/2025

Recruitment status
Not yet recruiting

Registration date
31/10/2025

Overall study status
Ongoing

Last Edited
29/10/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Children who wear fixed braces often find it difficult to clean their teeth properly, which can lead to problems with their teeth and gums. This study is looking at whether using a special mouthwash called ChloroStay™ can help improve dental care for children while they are having brace treatment.

Who can participate?
Children (12 -1 6 years) who are receiving routine hospital-based treatment with fixed braces may be invited to take part in the study.

What does the study involve?
All children in the study will continue brushing their teeth and gums with their usual toothbrush and toothpaste. Half of the children will also be asked to use the ChloroStay™ mouthwash as part of their daily routine. The study will follow their progress throughout their brace treatment.

What are the possible benefits and risks of participating?
Using the mouthwash may help improve the health of children's teeth and gums during brace treatment. There are no known serious risks, but as with any dental product, some children may experience mild side effects like irritation or dislike the taste.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
October 2025 to October 2028

Who is funding the study?
Schottlander and Davis Ltd, the company that developed the ChloroStay™ mouthwash.

Who is the main contact?
Professor Ama Johal, a.s.johal@qmul.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Ama Johal

ORCID ID
https://orcid.org/0000-0001-6841-227X

Contact details
Turner Street
Whitechapel
London
United Kingdom
E1 2AD
+44 2078828631
a.s.johal@qmul.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
365255

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effectiveness of ChloroStay mouthwash in optimising dental and gingival health during orthodontic treatment: a randomized controlled trial

Study objectives
The aim of the trial is to assess the ability of a Chlorhexidine mouthwash [ChloroStay™] to help maintain optimal dental and gum care during routine orthodontic treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)

notYetSubmitted, Ethics committee name not provided (Address not provided, City not provided, Zip/postal code not provided; Telephone number not provided; Email not provided), ref: Reference number not provided

Study design
Single-centre hospital-based randomized controlled clinical trial with parallel design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Optimal dental and gum care during routine orthodontic treatment

Interventions
Participants will be randomly assigned to intervention care [IC] and standardised care [SC] and assessed at baseline, 1-, 6- and 12-months, with the final scoring being at the removal of fixed braces [debond appointment].

Each participant will be instructed to maintain the recommended oral care for fixed appliance treatment, in which they are advised to clean their teeth using their regular toothbrush, an interdental brush and toothpaste twice daily [Standardized care Group].

Participants in the IC group will be issued with 3-month supply of ChloroStay Seven Day Mouthwash, along with the recommended instructions on use .

Participants will be randomised to receive either the ChloroStay Seven Day Mouthwash [Intervention care group] or standard oral care, as provided routinely to all participants undergoing fixed appliance treatment. Randomisation will be performed centrally, using a computer-generated randomisation sequence, by placing the randomisation sequences in opaque envelopes to ensure allocation concealment. Each participant will be anonymised and both the operator and participant blinded to treatment assignment

Intervention Type
Supplement

Primary outcome(s)
1. Age is measured using demographic questionnaire at baseline
2. Gender is measured using demographic questionnaire at baseline
3. Ethnicity is measured using demographic questionnaire at baseline
4. Visible plaque is measured using the Turesky modification of the Quigley–Hein plaque index at baseline, 1 month, 6 months, 12 months and debond
5. Gingival health is measured using the Loe and Silness gingival index at baseline, 1 month, 6 months, 12 months and debond
6. Intra-oral condition is measured using high-quality intra-oral photographs at baseline and debond
7. Supragingival plaque is measured using plaque sampling at baseline, 1 month, 6 months and 12 months

8. Alpha diversity of oral microbiome is measured using 16S rRNA gene amplicon sequencing at baseline, 1 month, 6 months and 12 months
9. Beta diversity of oral microbiome is measured using 16S rRNA gene amplicon sequencing at baseline, 1 month, 6 months and 12 months
10. Differential abundance of oral taxa is measured using 16S rRNA gene amplicon sequencing at baseline, 1 month, 6 months and 12 months
11. Functional acidogenicity is measured using standardised glucose challenge with pH recording at 0, 5, 10, 15 and 20 minutes at baseline, 1 month, 6 months and 12 months
12. Resting salivary pH is measured using titration or validated chairside kit score at baseline, 1 month, 6 months and 12 months
13. Salivary buffering capacity is measured using titration or validated chairside kit score at baseline, 1 month, 6 months and 12 months
14. Site-specific acidogenicity effects are measured using three-level mixed models at baseline, 1 month, 6 months and 12 months

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

Completion date
17/10/2028

Eligibility

Key inclusion criteria
1. Adolescents [12-16 years] of all ethnicity, socio-economic grouping and gender, for whom parents are able and willing to give informed consent
2. Planned to undergone a minimum of 12-months of fixed appliance treatment in both arches
3. Optimal dental health and oral hygiene prior to treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
16 years

Sex
All

Total final enrolment
52

Key exclusion criteria
1. Participants who have undergone previous course of fixed appliance treatment
2. Pre-existing clinical evidence of either enamel structural defects, demineralised lesions or fluorosis prior to commencement of treatment
3. Unwilling or unable to give consent
4. Inability to understand written and/or verbal English
5. Vulnerable individuals
6. Participation in other studies

Date of first enrolment
01/03/2026

Date of final enrolment
01/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Industry

Funder Name
Schottlander and Davis Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from [Professor Ama Johal ; email: a.s.johal@qmul.ac.uk] in a fully anonymised format, for a period of up to 3-years from completion of the study.

IPD sharing plan summary
Available on request