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Effect of two toothpastes on gingivitis

Submission date 09/09/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 18/09/2026	**Overall study status** Ongoing	
Last Edited 18/09/2026	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Gingivitis is a common plaque-induced inflammatory disease affecting gums. The response to the accumulation of bacteria on the tooth surface (also called plaque) results in signs and symptoms of inflammation, such as gum redness, swelling and bleeding. However, the consequences of this local gum inflammation may potentially extend systemically and could also lead, in predisposed individuals, to the more extensive destructive process of periodontitis. We know that oral hygiene instructions (OHI) and professional mechanical plaque removal by dentists are necessary procedures to stop and reverse gingivitis. In this context, finding additional interventions in the form of a toothpaste or mouthwash could give patient additional support. Corsodyl toothpaste has emerged as an important option for the treatment of gingivitis due to its formulation containing 67% sodium bicarbonate, which is a mild abrasive aiding plaque removal, and 0.31% w/w sodium fluoride.
This study seeks to test Corsodyl toothpaste against a commercially available standard toothpaste (Aquafresh) for improvement in gingivitis with oral hygiene instructions. In addition, we seek to test whether gingivitis has a systemic effect on inflammation by comparing levels of inflammatory biomarkers from gingival crevicular fluid (GCF, fluid collected around the gums) and blood samples.

Who can participate?
Patients aged 18-65 years with generalised gingivitis.

What does the study involve?
Participants will be invited to attend 4 research visits within 3 weeks, and will be randomised to one of the toothpastes. At weekly visits at Day 7, 14 and 21, progress will be checked and samples will be collected. The main outcome is improvement in gingivitis, and secondary outcomes include other oral health parameters, patient reported outcomes and levels of inflammatory biomarkers.

What are the possible benefits and risks of participating?
Benefits: While we don’t know whether either of the test toothpastes will help with gingivitis or whether one is better than the other, you may benefit from having regular oral exams to improve your gum health. You may also benefit from the information provided by the dentist about keeping your teeth and gums healthy.

Risks: There are no known serious side effects of using the toothpastes in the study as both are widely available to buy. Therefore, the study is considered safe. However, you may be inconvenienced by taking the time for the research visits. The oral examinations may be uncomfortable due to having your mouth open throughout and you may experience brief pain and bleeding when the dentist is examining you due to your swollen gums. This should get better if the gingivitis improves throughout the study.
Providing a blood sample can be uncomfortable for a short time and bruising at the site can sometimes occur.

Where is the study run from?
King's College London (UK).

When is the study starting and how long is it expected to run for?
October 2026 to May 2027.

Who is funding the study?
Haleon plc (UK).

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
370989

Central Portfolio Management System (CPMS)
75558

Study information

Scientific Title
Effectiveness of two different toothpaste formulations on gingival and systemic inflammation and patient-reported outcomes in patients with generalised gingivitis

Study objectives
Primary objective:
To assess the effect of toothpaste A (Corsodyl) vs toothpaste B (Aquafresh) in achieving reductions in gingival inflammation.
Secondary objectives:
1. To assess if a reduction in gingival inflammation is mirrored by reductions in systemic inflammation
2. To assess whether use of the test toothpaste is associated with patient-reported outcomes

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/08/2026, East of England - Cambridge South Research Ethics Committee (Equinox House City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8241; cambridgesouth.rec@hra.nhs.uk), ref: 26/EE/0196

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Gingivitis

Interventions
This is a superiority double-masked parallel-group RCT comparing patients receiving two different toothpastes for treatment of gingivitis. It will be a single centre trial in the Oral Clinical Research Unit (OCRU) at Guy's Dental Hospital.

Patients will be recruited from the Periodontal Department following periodontal assessment at Guy's Hospital or through volunteer advertisement. At the Day 1 visit (baseline), consent will be obtained and eligibility criteria will be checked to enrol the participant into the trial. Demographics and medical history (including dental history) will be obtained and a baseline oral examination will be conducted by the study dentist. Participants will also be asked to complete an oral health questionnaire and provide samples. Once all baseline data have been collected, the participant will be randomised (1:1) to toothpaste A or B, and be given oral health instructions to follow throughout their time in the study.

Participants will come back once a week for three weeks to measure any improvement in gum health and to provide samples. The second and third visits (Day 7 and Day 14 post-randomisation) will follow a shortened oral exam procedure, and the last visit on Day 21 will repeat the more comprehensive oral exam done at the baseline visit. Safety data will be collected throughout.

The study dentist and the trial statistician will be blinded to the allocations.

Intervention Type
Other

Primary outcome(s)
1. Gingival inflammation measured using full-mouth bleeding on probing score (FMBS) at day 21 at baseline, day 21

Key secondary outcome(s)
1. Diagnosis of generalised gingivitis measured using oral examination at baseline and day 21
2. Other measures of periodontal inflammation measured using Probing Pocket Depth (PPD), Clinical Attachment Level (CAL), Full Mouth Plaque Score (FMPS) and Gingival In-dex (GI) at oral examination at baseline and day 21
3. Local inflammation measured using biomarker analysis of gingival crevicular fluid at baseline and day 21
4. Systemic inflammation measured using biomarker analysis of blood samples at base-line and day 21
5. Patient-reported outcome measures (PROMs) measured using the Oral Health Impact Profile-14 (OHIP-14) at baseline and day 21

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Patients with generalised gingivitis [full-mouth bleeding score (FMBS) > = 30% and all sites with PPD < = 3 mm] (Caton et al. 2018)
2. Age 18-65 years

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Clinical attachment loss > 1mm, compatible with presence of periodontitis stage II, III or IV (Papapanou et al. 2018)
2. Presence of considerable calculus deposits which, as judged by the examining dentist, would not allow correct oral hygiene procedures
3. Current smoking (or regular smoking in the last 5 years)
4. Current use of orthodontic appliances
5. Use of systemic antibiotics in previous 3 months (as this may affect baseline clinical assessments and inflammatory markers)
6. Use of mouthrinses in previous month (as this may affect baseline clinical assessments and inflammatory markers)
7. Known allergy to toothpaste components
8. Self-reported medical history of diabetes, cardiovascular disease or other systemic inflammatory/immune diseases potentially contributing to gingival diseases
9. Not currently in any trials which could affect gum and oral health (e.g. drug study) as determined by the study dentist

Date of first enrolment
01/10/2026

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
England
SE1 7EH

Sponsor information

Organisation
King's College London

Funder(s)

Funder type
Government

Funder Name
Haleon

Alternative Name(s)
Haleon plc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date