

How effective are toothpastes in improving tooth discoloration marks after brace treatment?

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| Submission date 13/05/2020 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 14/05/2020 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 29/12/2025 | Condition category Oral Health | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Young people undergo orthodontic treatment to improve the appearance of their teeth, smile and bite. It is therefore very sad to see so many of these teeth become harmed during brace treatment, leaving a permanent and visible mark, which becomes very easy to see after brace removal. Toothpaste is recommended and used daily and therefore remains a relatively easy method of improving the appearance of the teeth by lessening the visibility of these marks. Whilst traditional Fluoride containing toothpastes have been shown to have some beneficial effects, newer toothpastes which contain lower levels of fluoride but a greater potential to release this in a more gradual way, offer the possibility of greater improvements in reducing these defects in the teeth. We aim to assess how brushing your teeth with one of two different types of toothpaste can affect the appearance of the white spots defects, known as white spot lesions (WSL), that have developed on the teeth and become visible following the removal of your fixed brace.

Who can participate?

Adolescents [12-18 years], who have undergone a minimum of 12-months of fixed appliance treatment in both arches, with clinically identifiable WSL present on at least 1 of the maxillary and/or mandibular anterior teeth [first premolar to first premolar] at the time of removal of fixed orthodontic appliances.

What does the study involve?

Participants will be randomly allocated to receive intervention care (Bio-Min toothpaste) or standardised care (Conventional toothpaste) and will be assessed for the level of remineralisation at 1, 3, 6 and 9 months.

What are the possible benefits and risks of participating?

The benefits are that it will help us to better understand which toothpaste is more effective in improving the appearance of the white spot defects on the teeth. There are no expected risks to taking part in this study.

Where is the study run from?

Institute of Dentistry, Queen Mary, University of London (UK)

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

December 2019 to September 2026

Who is funding the study?

BioMin Technologies Limited (UK)

Who is the main contact?

Prof Ama Johal, a.s.johal@qmul.ac.uk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

284589

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 284589

Study information

Scientific Title

The effectiveness of Bio-Min toothpaste in the management of white spot lesions: a randomized control trial

Acronym

BMELT

Study objectives

A fluoride containing bioactive glass toothpaste does not lead to a greater reduction in visible post-orthodontic WSL compared with a standard toothpaste.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/09/2021, Wales Research Ethics Committee 6 Swansea (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 2922 941090; Wales.REC6@wales.nhs.uk), ref: 21/WA/0256

Study design

Interventional single center randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Enamel White Spot Lesions [WSL]

Interventions

Participants will be randomly assigned, using computer generated numbers, blindly to intervention care (Bio-Min toothpaste) or standardised care (Conventional toothpaste), and assessed for the level of remineralisation at 1-, 3-, 6- and 9-months.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Remineralisation of WSL measured using the method described by Willmot et al., [2000] as % change from baseline at 1, 3, 6 and 9 months

Key secondary outcome(s)

Time interval for remineralisation measured using the method described by Willmot et al., [2000] at 1, 3, 6 and 9 months

Completion date

01/09/2026

Eligibility

Key inclusion criteria

1. Age 12-18 years
2. Undergone a minimum of 12-months of fixed appliance treatment in both arches
3. Clinically identifiable WSL present on at least 1 of the maxillary and/or mandibular anterior teeth [first premolar to first premolar] at the time of removal of fixed orthodontic appliances

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

12 years

Upper age limit

18 years

Sex

All

Total final enrolment

14

Key exclusion criteria

1. 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

Date of first enrolment

01/09/2021

Date of final enrolment

01/12/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Queen Mary University of London
Institute of Dentistry
Turner Street
London
England
E1 2AD

Sponsor information

Organisation

Queen Mary University of London

ROR

<https://ror.org/026zzn846>

Funder(s)

Funder type

Industry

Funder Name

BioMin Technologies Limited

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Protocol article | | 10/09/2024 | 11/09/2024 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |