ISRCTN14479873 https://doi.org/10.1186/ISRCTN14479873

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

Submission date
13/05/2020

Recruitment status
No longer recruiting

Registration date
14/05/2020

Overall study status
Ongoing

Last Edited
29/12/2025

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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
Prof Ama Johal

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

Contact details
Office 6
4th Floor
Institute of Dentistry
Queen Mary University of London
Turner Street
London
United Kingdom
E1 2AD
+44 (0)20 7882 6616
a.s.johal@qmul.ac.uk

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes