ISRCTN56234764 https://doi.org/10.1186/ISRCTN56234764

Effectiveness of different cleaning agents for retainers

Submission date	Recruitment status	[X] Prospectively registered
19/10/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/11/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2024	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Current plain English summary as of 23/02/2022:
Background and study aims
After the completion of orthodontic treatment, patients undergo a retention phase to maintain the results. During this phase, an orthodontic retainer is used. The retainer is worn 24 hours a day except when eating, drinking, brushing and playing sports. Without adequate cleaning, retainers can accumulate plaque and bacteria, leading to gingival (gum) inflammation and disease. A study showed that saliva quantity and composition is affected during orthodontic treatment. A variety of alternative cleaning agents have been discussed of which were mostly tested on acrylic orthodontic appliances and prostheses. To date, however, few studies have been performed to investigate the effects of cleaning agents on thermoplastic retainers and changes in the oral environment. The aim of this study is to assess the effectiveness of different cleaning agents for retainers.

Who can participate?
Adults over the age of 18 who are fitted with a thermoplastic retainer

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group are asked to clean their retainers using tap water. Those in the second group are asked to clean using a provided toothpaste and the third group are asked to clean using Retainer Brite to clean their retainers. A detailed explanation, demonstration and written instructions will be provided. The study lasts 12 months in total. Participants saliva will be assessed during retainer fit and at 6 months and 12 months follow up. Participants also complete an assessment form during the 6 months and 12 months follow up appointment.

What are the possible benefits and risks of participating?
There is no risk of participating in this study as it is carried out during the regular follow up of treatment. The results of this study will benefit individuals, researchers, and the community with the advancement of knowledge and orthodontic practice. It will also show if the different cleaning agents influence saliva parameters and the patients' experience. It will also be

beneficial to practitioners to know the best cleaning agent with the least amount of bacteria which will support the recommendations for cleaning methods of orthodontic retainers in the future.

Where is the study run from?
Universiti Teknologi Mara (UiTM) (Malaysia)

When is the study starting and how long is it expected to run for?
September 2019 to December 2022

Who is funding the study?
Universiti Teknologi Mara (UiTM) (Malaysia)

Who is the main contact?
1. Dr Iman binti Azmuddin
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2. Dr Saraswathy Devi Sinniah
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Previous plain English summary:
Background and study aims
After the completion of orthodontic treatment, patients undergo a retention phase to maintain the results. During this phase, an orthodontic retainer is used. The retainer is worn 24 hours a day except when eating, drinking, brushing and playing sports. Without adequate cleaning, retainers can accumulate plaque and bacteria, leading to gingival (gum) inflammation and disease. A study showed that saliva quantity and composition is affected during orthodontic treatment. A variety of alternative cleaning agents have been discussed of which were mostly tested on acrylic orthodontic appliances and prostheses. To date, however, few studies have been performed to investigate the effects of cleaning agents on thermoplastic retainers and changes in the oral environment. The aim of this study is to assess the effectiveness of different cleaning agents for retainers.

Who can participate?
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Universiti Teknologi Mara (UiTM) (Malaysia)

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September 2019 to February 2022 (updated 12/05/2021, previously: November 2021)

Who is funding the study?
Universiti Teknologi Mara (UiTM) (Malaysia)

Who is the main contact?
1. Dr Iman binti Azmuddin
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of thermoplastic retainer cleansing agents and patient-reported outcome: a randomized controlled trial

Acronym
ETRCA

Study objectives
1. There is no significant difference in the presence of Mutans Streptococci (MS) between three cleansing agents
2. There is no significant difference in salivary parameters in unstimulated saliva
3. There is no significant difference in patient-reported outcome with different cleansing agents

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 29/09/2020, UiTM Research Ethics Committee (Research Management Centre (RMC), Office of Deputy Vice Chancellor (Research & Innovation) Universiti Teknologi MARA, Level 3, Bangunan Wawasan, 40450 Shah Alam, Selangor, Malaysia; +60 (0)355442049; recsecretariat@uitm.edu.my), ref: 600- TNCP1(5/1/6)

Study design
Single-center interventional single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of caries in patients wearing a thermoplastic retainer

Interventions
Current intervention as of 23/02/2022:
This trial is a randomized controlled trial with three parallel arms. Patients will be randomly allocated to either group A (tap water), group B (toothpaste), or group C (Retainer Brite). The list of randomisation will be generated using SPSS statistical software.

A detailed explanation, demonstration, and written instructions will be provided. The study lasts 12 months in total. Participants' saliva will be assessed during the retainer fitting and at 6 months and 12 months follow up. Participants also complete an assessment form during the 6 month and 12 month follow-up appointments.

Previous intervention:
This trial is a randomized controlled trial with three parallel arms. Patients will be randomly allocated to either group A (tap water), group B (toothpaste) or group C (Retainer Brite). The list of randomisation will be generated using SPSS statistical software.

A detailed explanation, demonstration and written instructions will be provided. The study lasts 6 months in total. Participants saliva will be assessed during the retainer fitting and at 3 months and 6 months follow up. Participants also complete an assessment form during the 3 months and 6 months follow up appointment.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 23/02/2022:
Bacterial count of Mutans Streptococci (MS) measured using colony counting method at retainer fit, 6, and 12 months post retainer fit

Previous primary outcome measure:
Bacterial count of Mutans Streptococci (MS) measured using colony counting method at retainer fit, 3 months and 6 months post retainer fit

Secondary outcome measures
Current secondary outcome measures as of 23/02/2022:
1. Saliva parameters (hydration, viscosity, pH and quantity) during retention measured using time and visual assessment of the transparency, volume and pH test strip indicator at retainer fit, 6, and 12 months post retainer fit
2. Patient-reported outcome measured using assessment form at 6 and 12 months post retainer fit

Previous secondary outcome measures:
1. Saliva parameters (hydration, viscosity, pH and quantity) during retention measured using time and visual assessment of the transparency, volume and pH test strip indicator at retainer fit, 3 months and 6 months post retainer fit
2. Patient-reported outcome measured using assessment form at 3 months and 6 months post retainer fit

Overall study start date
27/09/2019

Completion date
28/12/2022

Eligibility

Key inclusion criteria
1. Patients fitted with thermoplastic retainer
2. Over 18 years old
3. Caries free
4. Healthy periodontal status

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
33

Key exclusion criteria
1. Pregnant
2. Patients on medication
3. Smokers
4. Patients with systematic disease
5. Prosthetic tooth in retainer

Date of first enrolment
18/01/2021

Date of final enrolment
28/08/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Teknologi Mara
Department of Orthodontics
Faculty of Dentistry
Jalan Hospital
Sungai Buloh
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Sponsor information

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Funder(s)

Funder type
University/education

Funder Name
Institute of Research Management and Innovation, Universiti Teknologi MARA

Alternative Name(s)
Institute of Research Management & Innovation, IRMI, UiTM

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
28/04/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Available on request, Published as a supplement to the results publication