ISRCTN13889391 https://doi.org/10.1186/ISRCTN13889391

The effect of toothpaste on tooth cleaning and tooth sensitivity

Submission date	Recruitment status	[X] Prospectively registered
05/02/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/02/2020	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
24/10/2022	Oral Health	

Plain English summary of protocol

Background and study aims
The aim of this trial is to identify if our experimental toothpaste promotes a reduction in tooth sensitivity and plaque compared to a marketed benchmark toothpaste.

Who can participate?
Healthy volunteers aged 18 to 65 years with a minimum of 20 natural teeth and two sensitive teeth as determined by the study investigators

What does the study involve?
Participants will be recruited and attend a screening appointment to determine if they are suitable for participation in the study. All suitable participants will then enter an acclimatization period. During this time, they will be required to brush their teeth twice per day (morning and night) using toothpaste and toothbrush supplied by the study site. The acclimatization period will be for a minimum of one day and a maximum of two weeks between screening and the start of the use of the study toothpaste, the baseline appointment.

At the baseline appointment, participants will receive a tooth examination to confirming they are suitable to continue in the study. If they are suitable, participants will have the sensitivity of their teeth tested using pressure and cold air and the amount of plaque on their teeth will be assessed. Participants will also complete a quality of life questionnaire. Participants will then be allocated to receive either an experimental toothpaste or a standard commercially available toothpaste. For both toothpastes, participants will be instructed to apply a full brush head of toothpaste to a dry toothbrush and brush their teeth twice daily, morning and night, for two mins each time over two weeks. In the baseline visit, the participants will each use their assigned toothpaste under the supervision of the investigators and the tooth sensitivity assessments will be repeated 60 seconds after application.

Participants will then complete two follow-up appointments at four days and then two weeks. At both appointments, participants will complete a quality of life questionnaire and have their teeth examination and plaque and tooth sensitivity measured.

What are the possible benefits and risks of participating?
There are no direct benefits for the participants taking part in the study, but they may help the dental profession further their knowledge in the control of dental plaque and tooth sensitivity.

The risks for the participants taking part in the study are minimal. Participants may experience tooth discomfort during the sensitivity assessments. The assessments for tooth sensitivity require applying stimuli (touch and cold air) to their teeth which may cause a short sharp pain. The stimuli are of a short duration and are no different than the discomfort that may be experienced by the participants in everyday life, for example, by brushing their teeth with cold water, or having a cold drink.

Where is the study run from?
Clinical Trials Unit, Bristol Dental School and Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2019 to October 2020 (updated 19/08/2020, previously: December 2020)

Who is funding the study?
Sunstar Suisse (Switzerland)

Who is the main contact?
Prof. Nicola West
N.X.West@bristol.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Nicola West

ORCID ID
http://orcid.org/0000-0002-9127-5530

Contact details
Clinical Trials Unit
Bristol Dental School and Hospital
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY
+44 0117 3429638
N.X.West@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
266661

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-7760, IRAS 266661

Study information

Scientific Title
A clinical study investigating the benefits of a hydroxyapatite/potassium nitrite and aluminium lactate cosmetic toothpaste to help the discomfort associated with dentine hypersensitivity compared to a benchmark marketed toothpaste

Study objectives
An experimental hydroxylapatite/potassium nitrite and aluminium lactate toothpaste will have an increased effect to promote a healthy mouth with regards to the reduction of sensitive teeth from dentine hypersensitivity and reduction of plaque compared to a marketed benchmark toothpaste.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2020, South West - Frenchay Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; frenchay.rec@hra.nhs.uk; +44 0207 104 8029), REC ref: 20/SW/0036

Study design
Single-centre, investigator-blinded, two-arm, baseline-controlled randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Treatment

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

Oral health and tooth sensitivity

Interventions
Participants will be recruited and attend a screening appointment to determine eligibility. All eligible participants will be provided with the toothbrush, toothpaste and timing instructions for the acclimatization period. All participants will use an acclimatization product which is Signal Toothpaste (Unilever). Participants will apply a strip of this toothpaste to cover the head of the toothbrush provided and brush their teeth for one timed minute twice daily (morning and evening) for a minimum of one day and a maximum of two weeks between screening and baseline.

At the baseline appointment, participants will receive an Oral Soft Tissue (OST) examination to confirming the participant's continuing eligibility for the study. Confirmed eligible participants will have two sensitive teeth selected for treatment and undergo baseline tooth sensitivity (Schiff sensitivity scale score elicited by an evaporative (air) stimulus, tactile sensitivity score elicited by a Yeaple probe stimulus and dentin hypersensitivity) and plaque score assessments. Participants will also complete a baseline quality of life questionnaire. Participants will then be randomized to receive either experimental toothpaste or benchmark controlled toothpaste according to a table prepared by the study Statistician.

The experimental toothpaste is hydroxylapatite /potassium nitrite and aluminium lactate (calcium aluminium phosphate precipitate) and the benchmark control toothpaste is Sensodyne Daily Care. For both toothpastes, participants will be instructed to apply a full brush head of toothpaste to a dry toothbrush and brush their teeth twice daily, morning and night, for two mins over two weeks.

In the baseline visit, the participants will each use their assigned toothpaste under supervision and tooth sensitivity assessments will be repeated 60 s after application.

Participants will then complete two follow-up appointments at four days and two weeks respectively. At both appointments, participants will complete a quality of life questionnaire and undergo OST examination and plaque and sensitivity assessments.

Intervention Type
Other

Primary outcome measure
Tooth sensitivity assessed by Schiff sensitivity scale score elicited by an evaporative (air) stimulus at baseline and 4 days

Secondary outcome measures
1. Tooth tactile sensitivity assessed by tactile sensitivity score elicited by a Yeaple probe stimulus at baseline and 4 days.
2. Tooth sensitivity after immediate use assessed by Schiff sensitivity scale score elicited by an evaporative (air) stimulus and tactile sensitivity score elicited by a Yeaple probe stimulus at baseline and 60 s.
3. Long term tooth sensitivity assessed by Schiff sensitivity scale score elicited by an evaporative (air) stimulus and tactile sensitivity score elicited by a Yeaple probe stimulus at baseline and 2 weeks.
4. Dentin hypersensitivity relief assessed by visual analogue scale (VAS) at baseline, 60 s, 4 days and 2 weeks

5. Plaque assessed by quantitative light-induced fluorescence-digital (QLF-D) at baseline, 4 days and 2 weeks

Overall study start date
01/09/2019

Completion date
31/10/2020

Eligibility

Key inclusion criteria
1. Voluntary written informed consent given
2. Aged 18 to 65 years
3. Good general and mental health in the opinion of the investigator or medically qualified designee
a. No clinically significant and relevant abnormalities of medical history or oral examination
b. No condition that would impact on safety, wellbeing or ability to understand and follow study procedures and requirements
4. Understands and is willing, able and likely to comply with all study procedures and restrictions
5. Minimum of 20 natural teeth
6. 2 sensitive teeth as defined by Schiff scores 2/3 to evaporative stimuli
7. Minimum of two, non-adjacent accessible teeth (incisors, canines, pre-molars), that have signs of sensitivity, measured by qualifying tactile stimulus (Yeaple ≤ 20g) and evaporative air assessment (Schiff sensitivity score ≥ 2)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Approximately 150 will be screened to ensure approximately 90 subjects will be randomized to ensure 80 subjects complete the study (approximately 40 per treatment group). Approximately equal number of male and female gender will be recruited to the study in each group scoring 2 or 3 on a Schiff test to a cold air blast.

Total final enrolment
82

Key exclusion criteria
1. Known or suspected intolerance or hypersensitivity to the study materials (or closely related compounds) or any of their stated ingredients

2. Participation in another clinical study (including cosmetic studies) or receipt of an investigational drug within 15 days of the screening visit
3. Previous participation in this study
4. Recent history (within the last year) of alcohol or other substance abuse
5. An employee of the sponsor or members of their immediate family
6. An employee of the site for this protocol (the Bristol Dental School and Hospital) and associated with the Clinical Trials unit
6. Presence of chronic debilitating disease which, in the opinion of the investigator, could affect study outcomes.
7. Any condition which, in the opinion of the investigator, causes xerostomia
8. Dental prophylaxis within 4 weeks of screening
9. Tongue or lip piercing
10. Desensitizing treatment within 2 weeks of screening (professional sensitivity treatments and non-dentifrice sensitivity treatments)
11. Active periodontal disease
12. Teeth bleaching within 8 weeks of screening
13. Teeth with exposed dentine but used as abutments for fixed or removable partial dentures, teeth with full crowns or veneers, orthodontic bands or cracked enamel
14. Teeth with evidence of caries
15. Daily prescription of medication/treatments which, in the opinion of the investigator, could interfere with the perception of pain. Including but not limited to: analgesics, anticonvulsants, antihistamines that cause marked or moderate sedation, sedatives, tranquilizers, anti-depressants, and mood-altering and anti-inflammatory drugs.
16. Any subject who, in the judgment of the investigator, should not participate in the study

Date of first enrolment
09/03/2020

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Dental Clinical Trials Unit
Bristol Dental School and Hospital
University of Bristol
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY

Sponsor information

Organisation
University of Bristol

Sponsor details
Research Enterprise Development
1 Cathedral Square
Bristol
England
United Kingdom
BS1 5DD
+44 01174284077
research-governance@bristol.ac.uk

Sponsor type
University/education

Website
http://bristol.ac.uk/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Industry

Funder Name
Sunstar Suisse

Results and Publications

Publication and dissemination plan
Through peer-reviewed journal publication and presentation of results at an international dental conference. No additional documents are available.

Intention to publish date
28/02/2021

Individual participant data (IPD) sharing plan

The anonymised participant data (clinical scores and questionnaire) generated during the current study will be shared after the end of the study and will be stored in the publicly available University of Bristol Research Data Repository (https://data.bris.ac.uk/data/) with a DOI maintained for a minimum of 20 years. Data will be made available as restricted access to bonafide researchers who provide a methodologically sound proposal and evidence of ethical approval (if required), subject to the agreement of the University of Bristol Data Access Committee for analysis to achieve aims in the approved proposal. Proposals will also be subject to the prior written consent of the funder (Sunstar).

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/02/2021	17/03/2021	Yes	No
Dataset		04/11/2021	19/10/2022	No	No
Protocol file	version 5	13/07/2020	24/10/2022	No	No
HRA research summary			28/06/2023	No	No