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To compare patient experience using two ultrasonic scalers, a magnetostrictive stack scaler with a piezoelectric scaler, in the maintenance of periodontal stability

Submission date
08/02/2018

Recruitment status
No longer recruiting

Registration date
26/02/2018

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Periodontitis is a common dental disease which causes bleeding of the gums, gum shrinkage and bone loss around the teeth which may result in tooth loss if the condition is untreated. Tooth loss can impact on quality of life as it may become more difficult to chew and missing teeth can make people self-conscious of their appearance and less confident. Routine treatments for periodontal disease may include surgical or non-surgical procedures, followed by regular maintenance treatment. There is strong evidence that structured maintenance treatment and good oral hygiene help to maintain gum health and prevent tooth loss. Supportive periodontal maintenance treatment comprises of cleaning and plaque removal around the gum margin of affected teeth. This treatment is usually performed with powered ultrasonic scalers, although hand instruments can also be used. There are two types of ultrasonic device, magnetostrictive devices and piezoelectric scaler devices. One of the main differences between the two types of device is the way the 'dental cleaning' tip of the device vibrates on the tooth surface. The other difference between each device is the amount of water that is required during operation. For the magnetostrictive scaler, a large amount of cold water only is required. This is due to the handpiece heating during operation and needing cooling. For the piezoelectric device, the vibration is only at the cleaning tip, which means the handle doesn't need cooling. This device also has the ability to gently heat the water flowing through it. The aim of this study is to compare patient experience between the use of a piezoelectric ultrasonic scaler and a magnetostrictive ultrasonic scaler during regular maintenance treatment for patients who have periodontal disease.

Who can participate?
Patients aged 18 and over who are susceptible to periodontal disease

What does the study involve?
Participants are randomly allocated to receive supportive periodontal treatment using either the piezo or magnetostrictive scaler with either room temperature or warm water on the left

and right side of the mouth. Discomfort, noise and vibration during treatment are measured. Following the end of the study, the participants remain under the care of their Dental Practitioner and there is no change to their routine care as a result of participating in the study.

What are the possible benefits and risks of participating?
There are no direct benefits to the participants from taking part in the study, but they may help provide dental professionals with a greater understanding of patient experience during dental cleaning using scaling devices. The risks to the participants from taking part in the study are no greater than for standard tooth cleaning treatment using dental scaling devices. Participants may experience some pain or discomfort following treatment, but this is to be expected following this type of treatment and will be of short duration.

Where is the study run from?
Rhiwbina Dental Surgery (UK)

When is the study starting and how long is it expected to run for?
January 2017 to October 2018

Who is funding the study?
W & H Burmoos GmbH

Who is the main contact?
Prof. Nicola West

Contact information

Type(s)
Scientific

Contact name
Prof Nicola West

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WH/NW – 11/16

Study information

Scientific Title
To compare patient experience using two ultrasonic scalers, a magnetostrictive stack scaler with a piezoelectric scaler, in the maintenance of periodontal stability

Study objectives
1. To determine patient experience (pain/discomfort, vibration, noise) during ultrasonic tooth scaling as part of a periodontal maintenance visit using a piezo-device compared to a magnetostrictive-device with room temperature water used in both devices for irrigation. The primary outcome measure is discomfort
2. To determine patient experience (pain/discomfort, vibration, noise) during ultrasonic tooth scaling as part of a periodontal maintenance visit using a piezo-device irrigated by warm water compared to a magnetostrictive-device with room temperature water for irrigation. The primary outcome measure is discomfort

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Bristol Health Sciences Faculty Research Ethics Committee, 12/12/2017, ref: 59162

Study design
Single-centre blinded (with respect to the patient) randomised split-mouth crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Periodontal disease

Interventions
Eligible participants will be randomly allocated to receive one of 4 treatment regimens, according to a predetermined randomisation schedule (2 treatments, 1 study visit – split mouth).

The allocated treatment regimen will be assigned in order of participants being recruited. The treatment procedures are as follows:

A1: right side: Tigon+ with room temperature water (~20-22°C), left side: Cavitron with room temperature water (~20-22°C)
A2: right side: Cavitron with room temperature water (~20-22°C), left side Tigon+ with room temperature water (~20-22°C)
B1: right side: Tigon+ with warm water (~36-37°C), left side: Cavitron with room temperature water (~20-22°C)
B2: right side: Cavitron with room temperature water (~20-22°C), left side: Tigon+ with warm water (~36-37°C)

Supportive periodontal treatment will be performed on both sides of the mouth using either the piezo or magnetostrictive scaler on the left or right side of the mouth depending on the treatment regimen the participant is assigned to. In all participants, the left side of the mouth will always be assessed first for consistency. There will only be one study visit for the participant to attend to complete the study. Both treatments will be performed at the same visit on the allocated side of the mouth. Following the end of the study, the participants will remain under the care of their Dental Practitioner and there will be no change to their routine care as a result of participating in the study.

Intervention Type
Procedure/Surgery

Primary outcome measure
Patient experience (pain/discomfort, vibration, noise) during ultrasonic tooth scaling comparing the devices with the use of room temperature water. Measured using VAS score lines immediately following treatment of each side of the mouth.

Secondary outcome measures
Patient experience (pain/discomfort, vibration, noise) during ultrasonic tooth scaling using a piezo-device irrigated by warm water compared to a magnetostrictive-device with room temperature water for irrigation. Measured using VAS score lines immediately following treatment of each side of the mouth.

Overall study start date
06/01/2017

Completion date
26/10/2018

Eligibility

Key inclusion criteria
1. Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent and has received a signed and dated copy of the informed consent form
2. Aged at least 18 years
3. Understands and is willing, able and likely to comply with all study procedures and restrictions
4. Susceptible to periodontal disease and have stability of the periodontium on examination (in supportive periodontal phase of treatment)

5. Good general health with (in the opinion of the investigator) no clinically significant and relevant abnormalities of medical history or oral examination

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Sufficient participants susceptible to periodontal disease in maintenance phase will be screened by the study site so that at least 140 participants who fulfil all entry criteria will be randomised to one of 4 groups, 35 each group.

Total final enrolment
140

Key exclusion criteria
1. Current or recurrent disease/dental pathology that could affect the assessments
2. Current or relevant previous history of serious, severe or unstable physical or psychiatric illness, or any medical disorder that may require treatment or make the participant unlikely to fully complete the study, or any condition that presents undue risk from the study products or procedures
3. Allergy/Intolerance Known or suspected intolerance or hypersensitivity to the study materials (or closely related compounds) or any of their stated ingredients
4. Participation in another clinical study or receipt of an investigational drug within 10 days of the screening visit
5. Personnel A member of the study site or a family relative. The study site for this protocol is the Clinical Trials Unit in the Bristol Dental School and Hospital and a Specialist Periodontal Practice. Employees of the sites are not eligible to participate
6. Any participant who, in the judgement of the investigator, should not participate in the study

Date of first enrolment
01/02/2018

Date of final enrolment
28/09/2018

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Rhiwbina Dental Surgery
25-27 Heol y Deri
Cardiff
United Kingdom
CF14 6HB

Sponsor information

Organisation
University of Bristol

Sponsor details
Senate House
Tyndall Avenue
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Industry

Funder Name
W & H Burmoos GmbH

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 11/02/2019:
The data has been submitted as an abstract to be presented at the International Association of Dental Research conference in Vancouver Canada 2019.

Previous publication and dissemination plan:
It is planned that the study will be written up and published in a high-impact peer reviewed journal. This will be approximately a year following data analysis following the end of the study.

Intention to publish date
26/10/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2020	14/01/2020	Yes	No
Protocol file	version 2.0	22/11/2017	25/10/2022	No	No