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A study to test the effect of a new treatment designed to improve the outcome of periodontal surgery

Submission date
10/11/2014

Recruitment status
No longer recruiting

Registration date
25/11/2014

Overall study status
Completed

Last Edited
24/07/2020

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Periodontitis is a very common chronic gum infection with many causes that damages the soft tissue and destroys the bone supporting the teeth. It can lead to tooth loss, difficulties chewing, poor appearance of teeth and gums and it can even increase the risk of a heart attack or stroke. Treatments can be surgical, where the gum is raised so that the tooth can be cleaned, or non-surgical, where the cleaning is done without the gum being raised. If surgical treatment is required, bone rebuilding procedures can also be performed in cases where some if the bone around the tooth has been destroyed. A new way of aiding the rebuilding and healing of tissue around teeth following surgery is with the use of a product from the patient's own blood called PRGF (plasma rich in growth factors, marketed as PRGFEndoret). It is known that PRGF helps tissue healing and minimises postoperative complications such as pain and inflammation /swelling. Blood from the patient's vein is taken before they have their surgery. The blood is treated and heated to form a gel like structure which is then inserted around the diseased tooth at the treatment site. The PRGF then acts on the surrounding tissues to aid healing and regeneration. The aim of this study is to investigate wound healing and regeneration of bone in patients with periodontal bone defects following surgical use of PRGF compared to surgical treatment without PRGF.

Who can participate?
Patients aged at least 18 who have two bony defects caused by periodontal disease (vertical interproximal bony defects) requiring surgical treatment

What does the study involve?
For each participant taking part in the study, one of the bony defects is randomly chosen to be treated with PRGF and the other is treated using standard surgical procedures. All participants receive the same two treatments, one for each defect.

What are the possible benefits and risks of participating?
While it is not certain the PRGF will improve results, previous studies in which PRGF has been used in other oral surgical procedures have shown it to be beneficial in reducing inflammation

and healing times. The risks of taking part in the study are no greater than that of standard periodontal surgery, with some pain or discomfort likely but normal for this type of procedure.

Where is the study run from?
Bristol Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2014 to April 2015

Who is funding the study?
University of Bristol (UK)

Who is the main contact?
Prof. Nicola West

Contact information

Type(s)
Scientific

Contact name
Prof Nicola West

Contact details
Clinical Trials Unit (Periodontology)
Bristol Dental School and Hospital
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Additional identifiers

Protocol serial number
BTI/NW - 0913 (sponsor Ref 2119)

Study information

Scientific Title
The effect of Plasma Rich in Growth Factors (PRGF) on periodontal tissue regeneration

Acronym
N/A

Study objectives
Aim:
To investigate the effect of surgical placement of PRGF (marketed as PRGF/Endoret®) on enhancing tissue regeneration in patients with vertical interproximal periodontal defects compared to surgical treatment without the placement of PRGF.

Objectives:
1. The primary objective of this study is to determine whether PRGF (marketed as PRGF /Endoret®) supports the predictable regeneration of the lost periodontal tissues (hard and soft) caused by periodontitis by measuring clinical attachment levels.
2. The secondary objective is to determine whether the use of PRGF (marketed as PRGF /Endoret®) in periodontal regeneration surgery is more effective than a conventional surgical approach alone in improving clinical attachment loss measuring by clinical attachment levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West- Central Bristol, 20/06/2014, ref. 14/SW/0114

Study design
Single-centre single-blind randomised two treatment regimen split-mouth study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Interventions:
1. Surgical treatment of the vertical interproximal periodontal defect will be performed using open flap debridement and planing of the root surface using standard operating techniques. Following the procedure, the elevated mucoperiosteal flap will be repositioned and sutured.
2. Where the defect is randomised to receive the adjunctive use of PRGF (marketed as PRGF /Endoret®), the root surface and the bone defects will be irrigated with recently activated Fraction 2 of PRGF and thence after a PRGF clot will be inserted to fill the bony defect. A fibrin membrane will then be applied to cover the surgical area and the elevated mucoperiosteal flap repositioned and sutured.

The preparation of plasma rich in growth factors (PRGF) will be performed using the PRGF /Endoret®1 dental kit. The PRGF will be collected, processed and administered within a single surgical procedure within the confines of a surgical room where there are no other samples being processed at the same time.

1. PRGF preparation
1.1. Preparation of the blood sample:
Immediately prior to each surgical treatment, the participants will supply a sample of their own blood which will be collected by the study clinician. Participants will be advised to have a light meal approximately an hour prior to their appointment. Venous blood will be withdrawn from the participant using 9 ml tubes (which contain 0.9 ml of 3.8% sodium citrate as anticoagulant). Approximately 4 6 tubes of blood will be withdrawn. The blood will be centrifuged using the PRGF® System Centrífuge IV® at 580 g for 8 minutes at room temperature. The blood will be separated into red blood cells at the bottom of the tube and plasma at the top of the tube

(Figure 1). The plasma column above the red blood cells will be separated into 2 fractions with a PRGF® Plasma Transfer Device. Fraction 1 (F1) is calculated by subtracting 2 mL from the volume of the plasma column above the buffy coat. Fraction 2 (F2) is the 2 mL of plasma just above the buffy coat. During the collection of F2, attention will be paid not to include leukocytes in the PRGF (the buffy coat).
1.2. Preparation method of PRGF:
The activation of PRGF will be accomplished with PRGF activator (10% calcium chloride). The volume of the PRGF to activate will be determined according to the size of the vertical interproximal bony defect to fill. The PRGF clot that will be used to fill the bony defect will be prepared from the F2 of the PRGF. For that, PRGF activator will be added to F2 at ratio of 50 µL of PRGF activator per each 1 mL of F2. The clot will need 10 to 15 minutes to form. For this, the activation step will be performed 10-15 minutes before the placement of clot in the bony defect. Fraction 1 (F1) will be used to form fibrin membrane that will be used to cover the bony defect after filling. The activation procedure is the same as described for F2.
1.3. Application of PRGF:
Recently activated F2 of PRGF will be used to irrigate the root surface and the bone defects. The PRGF clot from F2 will be used to fill the vertical interproximal bony defect and then a fibrin membrane prepared from F1 will be placed to cover the defect before the flap closure and suturing.

Each intervention will only administered once.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The change in clinical attachment (pocket depth and gingival recession) measured in mm at the final visit. Measured at 1-2 weeks and 8-12 weeks

Key secondary outcome(s))
Pain assessed by VAS score in mm at 1-2 weeks and 8-12 weeks

Completion date
24/04/2015

Eligibility

Key inclusion criteria
1. Consent 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 old
3. Understands and is willing, able and likely to comply with all study procedures and restrictions
4. Good general health with (in the opinion of the investigator) no clinically significant and relevant abnormalities of medical history or oral examination
5. Oral Cavity - Have at least 2 vertical interproximal periodontal defects in different quadrants of the mouth as evidenced by radiographic investigation
6. Oral Hygiene Status - Full mouth Turesky plaque index score <2
7. Non-Smoker - Participant must be a non-smoker or have stopped smoking for 6 months prior to surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
38

Key exclusion criteria
1. Women who are known to be pregnant or who are intending to become pregnant over the duration of the study
2. Women who are breastfeeding
3. Disease:
3.1. Current or recurrent disease/dental pathology that could affect the assessments
3.2. Bleeding disorders
3.3. Immuno-compromised
3.4. 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
3.5. Tooth with >grade I mobility
4. Allergy/Intolerance Known or suspected intolerance or hypersensitivity to the study materials (or closely related compounds) or any of their stated ingredients
5. Medication: Use of antibiotics one month prior to start of the study
6. Clinical Study/Experimental Medication: Participation in another clinical study or receipt of an investigational drug within 10 days of the screening visit
7. Substance abuse Recent history of alcohol or other substance abuse
8. 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. Employees of the Bristol Dental School and Hospital not associated with the Clinical Trials Unit are eligible to participate
9. Any participant who, in the judgement of the investigator, should not participate in the study

Date of first enrolment
01/10/2014

Date of final enrolment
24/04/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Dental School and Hospital
Bristol
United Kingdom
BS1 2LY

Sponsor information

Organisation
University of Bristol (UK)

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
University/education

Funder Name
University of Bristol

Alternative Name(s)
Universitas Bristolliensis, bristoluniversity, bristoluni

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2018	24/07/2020	Yes	No
HRA research summary			28/06/2023	No	No