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Platelet rich fibrin in periodontal surgery

Submission date
17/10/2018

Recruitment status
No longer recruiting

Registration date
23/11/2018

Overall study status
Completed

Last Edited
19/12/2018

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Periodontitis is a chronic inflammatory disease that causes resorption of the alveolar bone in unpredictable pattern. It can be treated successfully, but sometimes bone defects remain. These defects can prevent the complete resolution of the periodontal inflammation and are a risk factor for future progression of the disease, leading to tooth loss.The lack of bone among the roots, called furcation area, is an indicator for tooth loss in the long term.
The treatment of these bone defects is surgical, and can be performed removing and remodeling the tissues, with sacrifice of healthy bone and tooth structure, or with the attempt to recreate new bone. This last approach is called regenerative approach, and has generated high interest in the last 20 years.
Platelet Rich Fibrin (PRF) is a new material based on fibrin, which can be obtained from the blood of the patient. PRF has been demonstrated to be beneficial in wound healing, as the platelets and white blood cells can lead to the release of growth factors. Therefore, its use in periodontal regenerative surgery can be beneficial.
Enamel Matrix Derivative (EMD) is one of the most used materials for periodontal regeneration. EMD has been widely studied in the regeneration of periodontal infrabony defects, but there is limited evidence about the application of EMD in molar teeth with furcation involvement.
Therefore, our primary aim is to evaluate the possible additional benefit of the newest PRF technique (A-PRF+) with open flap debridement (OFD) in comparison to the application of EMD with OFD in periodontal regeneration surgery.

Who can participate?
People aged 18-80 years of age with one molar with furcation involvement who are being treated for peridontitis at the Department of Periodontology of ACTA

What does the study involve?
Participants will be randomly allocated to receive A-PRF+ and OFD, EMD and OFD or OFD only. During the surgery, participants will have samples of blood and fluid taken. This will also be done again at various points following the surgery. Participants will be assessed for a variety of factors, including probing depth, wound healing, bone fill and acceptance of the procedure.

What are the possible benefits and risks of participating?
The possible benefit of participating is that the results of this trial may help to create and improve new methods for peridontal regenerative surgery. The possible risks of participating are the standard risks associated with OFD and blood sampling.

Where is the study run from?
Department of Peridontology, ACTA (Netherlands)

When is the study starting and how long is it expected to run for?
December 2017 to June 2021

Who is funding the study?
Department of Periodontology, ACTA (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL6265602917

Study information

Scientific Title
Furcation involvement reduction after platelet rich fibrin application in the surgical treatment of periodontal patients with furcation II involved molars, compared to open flap debridement and Emdogain: a randomised clinical trial

Study objectives
Platelet Rich Fibrin(PRF) is better than Emdogain® (EMD) and Open Flap Debridement (OFD) in the regenerative treatment of molars with furcation II involvement

Ethics approval required
Old ethics approval format

Ethics approval(s)
Vrij Universiteit Medical Center, 01/05/2018, 2018.055

Study design
Interventional single-centre double-blind three-armed randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Periodontal disease
Localized deep pockets on furcation grade II involved molars

Interventions
Participants will be randomly allocated using software and stratified based on whether they are smokers or non-smokers. They will be randomly allocated to one of the following treatment modalities:
1. Open Flap Debridement (OFD) and Platelet Rich Fibrin (PRF)
2. OFD and Emdogain® (EMD)
3. OFD alone (standard treatment)
The treatment will last for a period of 90 minutes. Follow-up measurements will be performed after 6 months. Examiners and participants will be blinded regarding the type of treatment performed.

Intervention Type
Procedure/Surgery

Primary outcome measure

The following are assessed at the baseline and at the 6 month follow-up using a Nabers probe:
1. Change in Horizontal Clinical Attachment Level (HCAL),
2. Furcation involvement

Secondary outcome measures
The following are assessed at the baseline and at the 6 month follow-up (unless otherwise stated):
1. Change in Vertical Clinical Attachment Level (VCAL), assessed using the Michigan O periodontal probe with Williams markings. VCAL is defined as the distance between the cement-enamel junction and the bottom of the periodontal pocket
2. Change in Probing Pocket Depth (PPD), assessed using the Michigan O periodontal probe with Williams markings. PPD is defined as the distance between the sulcus and the bottom of the periodontal pocket
3. Bleeding on probing (BOP), assessed by the number of gingival units that bleed upon probing. Bleeding sites are scored as 0 = no bleeding, 1 = pinprick bleeding and 2 = excessive bleeding
4. Bone fill, assessed using the Michigan O peridoontal probe with Williams markings. Bone fill is expressed as the difference between this measurement at the baseline and at the 6 month follow-up
5. Wound healing, assessed using the Early Wound Healing Index (EWHI) and recorded with intraoral clinical photographs at days 3, 7 and 14, week 6 and month 3 post-surgery
6. Postoperative morbidity, assessed using questionnaires (visual analogue score (VAS)) at the end of the day, daily, for the first week post-surgery, and then at day 14, week 6 and month 3 post-surgery.
7. Acceptance of procedure, assessed using the post-operative questionnaire after surgery
8. Biomarkers in gingival crevicular fluid (GCF) and peripheral blood as a possible predictor of early and long-term clinical wound healing. GCF will be collected using a paper strip from the sulcus of the deepest pocket at the baseline and at days 3, 7 and 14, week 6, and 3 and 6 months post-surgery. The following biomarkers will be analysed:
8.1. Albumin (as a reference parameter to measure the relative amount of other proteins)
8.2. Growth factors, including VEGF, EGF, IGF and PDGF
8.3. Inflammatory cytokines, including IL-1, IL-2, IL-12, TNF-α, TGF-β, matrix metalloproteinases (MMPs)

Overall study start date
01/12/2017

Completion date
01/06/2021

Eligibility

Key inclusion criteria
1. Aged 18-80 years
2. Presence of at least one molar with furcation involvement 2, with horizontal CAL >3 mm and residual pocket after non-surgical therapy of ≥5 mm
3. < 20 % full mouth plaque score (FMPS)
4. < 30 % full mouth bleeding score (FMBS)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
69

Key exclusion criteria
1. Uncontrolled diabetes
2. HIV
3. Leukopenia
4. Any systemic diseases related to reduced healing potential
5. Allergy to any medication related with the study protocol (paracetamol, xilocaine)
6. Pregnancy or lactation
7. Daily use of any medication suppressive for the immune system (corticosteroid or immunosuppressant)
8. Antibiotics use before the study enrolment
9. Third molars
10. Terminal bone loss
11. Endodontically and non-endodontically treated teeth with periapical radiolucency
12. Periapical radiolucency or vertical fracture.
13. Tooth mobility >1
14. Furcation involvement grade 0, 1 or 3

Date of first enrolment
01/08/2018

Date of final enrolment
01/01/2021

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Periodontology, Academic Centre for Dentistry Amsterdam (ACTA) University of Amsterdam (UVA) and Vrije Universiteit (VU) Amsterdam
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Sponsor information

Organisation
Academic Centre for Dentistry Amsterdam (ACTA) - Department of Periodontology

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University/education

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ROR
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Funder(s)

Funder type
University/education

Funder Name
Academic Centre for Dentistry Amsterdam (ACTA) - Department of Periodontology

Results and Publications

Publication and dissemination plan
This clinical study will possibly produce 2 articles:
1. Clinical results and comparison of the clinical measurements with GCF samples values
2. Correlation between wound healing and blood markers

Intention to publish date
03/01/2021

Individual participant data (IPD) sharing plan

Clinical preliminary data will be available when half of the patients are treated. The data will be available until the publication of the study.
Data will be shared with other researcher for research purpose (e.g. meta-analysis), in form of a table that cannot be modified.
Informed consent from participants is obtained and always available for legal purposes.

IPD sharing plan summary

Available on request