

# Platelet rich fibrin in periodontal surgery

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| <b>Submission date</b><br>17/10/2018   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>23/11/2018 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>30/01/2026       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data  |

## 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 periodontitis 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 periodontal 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 Periodontology, 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?

Luciano Pitzurra

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## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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 periodontal 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- $\alpha$ , TGF- $\beta$ , matrix metalloproteinases (MMPs)

### **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  $\geq 5$  mm
3. < 20 % full mouth plaque score (FMPS)
4. < 30 % full mouth bleeding score (FMBS)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

### **Upper age limit**

80 years

### **Sex**

All

### **Total final enrolment**

0

### **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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Amsterdam

Netherlands

1081 LA

## **Sponsor information**

**Organisation**

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

**ROR**

<https://ror.org/04x5wnb75>

## **Funder(s)**

**Funder type**

University/education

## Funder Name

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

## Results and Publications

### 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

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 31/07/2023   | 30/01/2026 | Yes            | No              |