ISRCTN10907678 https://doi.org/10.1186/ISRCTN10907678

# Bone proteins in the treatment of periodontal diseases

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 28/10/2022 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 06/11/2022 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 29/12/2023 | Oral Health | |

## Plain English summary of protocol

Background and study aims
The advent of recently developed techniques and the availability of biomaterials, such as the use of enamel matrix protein derivatives (EMD), recombinant human platelet-derived growth factor (rhPDGF), and hyaluronic acid (HA), have provided both clinicians and researchers with sophisticated therapeutic options for the management of Grade II furcation-type defects (bone loss, usually as the result of periodontal disease, affecting the base of the root trunk of a tooth where several roots meet). The use of these biomaterials in combination with either bone graft substitutes or membranes aimed at guided tissue regeneration has been considered an effective modality when treating infrabony defects (at the base of the tooth pocket relative to the bone crest) and Grade-II furcation-type lesions. The use of biodegradable membranes to promote periodontal regeneration has been reported. The properties of the biodegradable membrane should permit selective repopulation of periodontal ligament (PDL) cells onto the root surfaces, followed by degradation only when this process is complete. Polylactic acid/polyglycolic acid (PLA/PGA) is a synthetic bioabsorbable membrane made from a co-polymer of lactide and glycolide. The time of degradation of PLA/PGA membrane (Polyglactin-910) was found to be 30-50 days and has been reported to facilitate periodontal regeneration. Hence, the current study protocol was designed to assess the performance of rhBMP-2 with PLA/PGA membrane through the reduction of horizontal and vertical defect depth with simultaneous gain in clinical attachment level to achieve periodontal tissue regeneration in Grade-II furcation-type defects.

Who can participate?
Patients with Grade II furcation defects

What does the study involve?
All patients undergoing treatment for Grade-II furcation-type defects will receive bioabsorbable PLA/PGA membrane to achieve periodontal tissue regeneration. Teeth randomly assigned to the test group will also receive an application of rhBMP-2. Periodontal regeneration will be assessed in both groups using dental probes at baseline, 3 months and 6 months postoperatively.

What are the possible benefits and risks of participating?
Possible benefits of participating include:
1. Active participation in their periodontal health care

2. Gaining access to new treatments before they are widely available
3. A team of dentists who will provide them with regular and attentive dental therapy
4. Contribution to dental research to help others
Possible risks of participating include:
1. A small chance of minor discomfort that will only last a short time
2. The study may require more time and attention than standard treatment would, including visits to the study site

Where is the study run from?
Sharad Pawar Dental College & Hospital (India)

When is the study starting and how long is it expected to run for?
March 2016 to September 2019

Who is funding the study?
Sharad Pawar Dental College & Hospital (India)

Who is the main contact?
Dr Kiran Kumar Ganji
dr.kiran.ganji@jodent.org

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Kiran Kumar Ganji

### ORCID ID
https://orcid.org/0000-0002-3178-9513

### Contact details
Department of Periodontics & Implantology
Sharad Pawar Dental College & Hospital
Sawangi Meghe
Wardha
Nagpur
India
442001
+919225755282
dr.kiran.ganji@jodent.org

# Additional identifiers

# Study information

### Scientific Title

Evaluation of the effectiveness of recombinant human bone morphogenic protein 2 (rhBMP-2) in combination with bioresorbable membrane (PLA/PGA) for periodontal regeneration in grade II furcation defects: a clinical study

## Study objectives
Recombinant human bone morphogenic protein 2 (rhBMP-2) along with a PLA/PGA membrane, does not contribute to gain in clinical attachment levels for Grade-II furcation type defects (if compared to the sole use of a PLA/PGA membrane), and it does not lead to differing results regarding the vertical and horizontal defect depths, or the extent of gingival recessions.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 02/09/2016, Institutional Ethics Committee (Datta Meghe Institute of Medical Sciences, Nagpur, India; +917152 287701; medical_ivda@sancharnet.in), ref: DMIMS(DU)/IEC /1527

## Primary study design
Observational

## Study design
Single-centre longitudinal case-control 6-month study

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Regenerative periodontal therapy in the management of furcation defects caused due to periodontal diseases

## Interventions
After achieving adequate anesthesia, intra-crevicular incisions were given on the buccal surfaces of teeth, including one tooth adjacent (mesial and distal) to access the furcation defect for treatment. The incisions were made as inter-proximally as possible, for the preservation of the inter-dental papilla, to obtain primary closure of the wound. The releasing incisions were given when needed with the aim to achieve adequate accessibility, and also gain coronal displacement of the periodontal flap. A mucoperiosteal flap was then reflected using a periosteal elevator. The pocket epithelium was curetted out carefully. The furcation defect was debrided, and the roof of the defect and the exposed surfaces of the root were scaled and planed using hand instruments as well as ultrasonic instruments.
Following these intraoperative measurements, the confirmed defects were randomly assigned to test (n = 12) and control groups (n = 12) by using a computer-generated blocked randomization list (Randlist, DatInf), thus referring to the pre-sealed envelopes. In the test group, the flap was pre-sutured without placing a knot in order to allow for rapid wound closure following the placement of the PLA/PGA membrane with rhBMP-2. A bioabsorbable PLA/PGA membrane (BioMesh-s, Samyang Biopharma) was trimmed in order to conceal the lesion, extending approximately 2 mm beyond the edges of the furcation defect. In the control group (PLA/PGA alone), the membrane was trimmed and placed over the defect in a manner similar to the test group, except without the application of rhBMP-2.

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
1. Relative clinical attachment level measured using Williams graduated periodontal probe and numerical values were recorded into a Microsoft Excel spreadsheet at baseline, 3 months and 6 months postoperatively
2. Vertical probing depth measured using Williams graduated periodontal probe and numerical values were recorded into a Microsoft Excel spreadsheet at baseline, 3 months and 6 months postoperatively
3. Horizontal probing depth measured using Nabers graduated furcation probe and numerical values were recorded into a Microsoft Excel spreadsheet at baseline, 3 months and 6 months postoperatively
4. Relative gingival margin level measured using Williams graduated periodontal probe and numerical values were recorded in a Microsoft Excel spreadsheet at baseline, 3 months and 6 months postoperatively

### Key secondary outcome(s)
Periodontal regeneration was assessed by clinical attachment gain, vertical probing depth reduction and horizontal probing depth reduction which were measured using Williams graduated periodontal probe and numerical values were recorded into a Microsoft Excel spreadsheet at baseline, 3 months and 6 months postoperatively

### Completion date
26/09/2019

## Eligibility

### Key inclusion criteria
1. Grade II furcation defects
2. Furcation defects present in mandibular 1st molars
3. Systemically healthy
4. Furcation defects present on the buccal surface

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment
24

### Key exclusion criteria

1. Grade II furcation defects in second mandibular molars
2. Patients with past history of periodontal therapy
3. Former and current smokers

**Date of first enrolment**
26/01/2019

**Date of final enrolment**
24/02/2019

# Locations

**Countries of recruitment**
India

**Study participating centre**
**Sharad Pawar Dental College & Hospital**
Sawangi Meghe
Wardha
Nagpur
India
442001

# Sponsor information

**Organisation**
Sharad Pawar Dental College & Hospital

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Sharad Pawar Dental College & Hospital

# Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Kiran Kumar Ganji, dr.kiran.ganji@jodent.org. Qualitative and quantitative data will be shared. Written consent was obtained from the participants. Personal data has been encrypted by the identifiers to maintain privacy and also to remove the personally identifiable information of the participants.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 10/02/2023 | 29/12/2023 | Yes | No |