



Clinical Trial Details (PDF Generation Date :- Fri, 03 Dec 2021 14:08:21 GMT)

CTRI Number	CTRI/2020/06/026141 [Registered on: 25/06/2020] - Trial Registered Prospectively																	
Last Modified On	21/06/2020																	
Post Graduate Thesis	Yes																	
Type of Trial	Interventional																	
Type of Study	Dentistry																	
Study Design	Randomized, Parallel Group, Active Controlled Trial																	
Public Title of Study	A comparative study of evaluation of effect of injectable platelet rich fibrin with resorbable collagen membrane to resorbable collagen membrane alone for gingival recession coverage.																	
Scientific Title of Study	Comparative evaluation of effect of injectable platelet rich fibrin with collagen membrane to collagen membrane alone using vestibular incision subperiosteal tunnel access technique for gingival recession coverage : a split mouth randomised controlled clinical trial.																	
Secondary IDs if Any	Secondary ID	Identifier																
	NIL	NIL																
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	<table border="1"> <thead> <tr> <th colspan="2">Details of Principal Investigator</th> </tr> </thead> <tbody> <tr> <td>Name</td> <td>Laxmikanta Patra</td> </tr> <tr> <td>Designation</td> <td>MDS</td> </tr> <tr> <td>Affiliation</td> <td>SCB Dental College and Hospital, Cuttack</td> </tr> <tr> <td>Address</td> <td>Department of periodontics, SCB Dental College and Hospital, Cuttack. Cuttack ORISSA 753007 India</td> </tr> <tr> <td>Phone</td> <td>9861224842</td> </tr> <tr> <td>Fax</td> <td></td> </tr> <tr> <td>Email</td> <td>l.patra@rediffmail.com</td> </tr> </tbody> </table>		Details of Principal Investigator		Name	Laxmikanta Patra	Designation	MDS	Affiliation	SCB Dental College and Hospital, Cuttack	Address	Department of periodontics, SCB Dental College and Hospital, Cuttack. Cuttack ORISSA 753007 India	Phone	9861224842	Fax		Email	l.patra@rediffmail.com
Details of Principal Investigator																		
Name	Laxmikanta Patra																	
Designation	MDS																	
Affiliation	SCB Dental College and Hospital, Cuttack																	
Address	Department of periodontics, SCB Dental College and Hospital, Cuttack. Cuttack ORISSA 753007 India																	
Phone	9861224842																	
Fax																		
Email	l.patra@rediffmail.com																	
Details Contact Person (Scientific Query)	<table border="1"> <thead> <tr> <th colspan="2">Details Contact Person (Scientific Query)</th> </tr> </thead> <tbody> <tr> <td>Name</td> <td>Subash Chandra Raj</td> </tr> <tr> <td>Designation</td> <td>Associate Professor (PG In-Charge)</td> </tr> <tr> <td>Affiliation</td> <td>SCB Dental College and Hospital Cuttack</td> </tr> <tr> <td>Address</td> <td>Department of Periodontics, SCB Dental College and Hospital, Cuttack Cuttack ORISSA 753007 India</td> </tr> <tr> <td>Phone</td> <td>9437008298</td> </tr> <tr> <td>Fax</td> <td></td> </tr> <tr> <td>Email</td> <td>drsubash007@gmail.com</td> </tr> </tbody> </table>		Details Contact Person (Scientific Query)		Name	Subash Chandra Raj	Designation	Associate Professor (PG In-Charge)	Affiliation	SCB Dental College and Hospital Cuttack	Address	Department of Periodontics, SCB Dental College and Hospital, Cuttack Cuttack ORISSA 753007 India	Phone	9437008298	Fax		Email	drsubash007@gmail.com
Details Contact Person (Scientific Query)																		
Name	Subash Chandra Raj																	
Designation	Associate Professor (PG In-Charge)																	
Affiliation	SCB Dental College and Hospital Cuttack																	
Address	Department of Periodontics, SCB Dental College and Hospital, Cuttack Cuttack ORISSA 753007 India																	
Phone	9437008298																	
Fax																		
Email	drsubash007@gmail.com																	
Details Contact Person (Public Query)	<table border="1"> <thead> <tr> <th colspan="2">Details Contact Person (Public Query)</th> </tr> </thead> <tbody> <tr> <td>Name</td> <td>Laxmikanta Patra</td> </tr> <tr> <td>Designation</td> <td>MDS</td> </tr> <tr> <td>Affiliation</td> <td>SCB Dental College and Hospital Cuttack</td> </tr> <tr> <td>Address</td> <td>Department of Periodontics, SCB Dental College and Hospital, Cuttack. Cuttack ORISSA 753007 India</td> </tr> </tbody> </table>		Details Contact Person (Public Query)		Name	Laxmikanta Patra	Designation	MDS	Affiliation	SCB Dental College and Hospital Cuttack	Address	Department of Periodontics, SCB Dental College and Hospital, Cuttack. Cuttack ORISSA 753007 India						
Details Contact Person (Public Query)																		
Name	Laxmikanta Patra																	
Designation	MDS																	
Affiliation	SCB Dental College and Hospital Cuttack																	
Address	Department of Periodontics, SCB Dental College and Hospital, Cuttack. Cuttack ORISSA 753007 India																	



Phone	9861224842			
Fax				
Email	l.patra@rediffmail.com			
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> SCB Dental College and Hospital, Cuttack, Odisha. Pin-753007			
Primary Sponsor	Primary Sponsor Details			
Name	SCB Dental College and Hospital Cuttack			
Address	SCB Dental College and Hospital, Cuttack, Odisha. Pin-753007			
Type of Sponsor	Government medical college			
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Laxmikanta Patra	SCB Dental College and Hospital, Cuttack	Department of periodontics, SCB Dental College and Hospital, Cuttack Cuttack ORISSA	9861224842 l.patra@rediffmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	INSTITUTIONAL ETHICS COMMITTEE(IEC) SCB DENTAL COLLEGE AND HOSPITAL CUTTACK,ODISHA	Approved	17/09/2019	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Other periodontal diseases	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Injectable platelet rich fibrin with collagen membrane	Xenograft collagen membrane soaked with autogenous injectable platelet rich fibrin is inserted through the access incision on test side and followup is done for 6 months.	
	Comparator Agent	Collagen memmbrane	Xenograft collagen membrane is inserted through the access incision on the control site and followup is done for 6 months.	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	50.00 Year(s)		
	Gender	Both		
	Details	1. Both males and females of age ? 18 yrs with dental hypersensitivity or impaired aesthetics associated with the		



	recession. 2. Miller Class I or II bilateral buccal gingival recession defects measuring ? 2 mm on the anterior teeth or premolars, on either arch. 3. Identifiable CEJ at recession sites. 4. Subjects not under any medications known to interfere with periodontal tissue health or healing. 				
Exclusion Criteria	<table border="1"> <thead> <tr> <th colspan="2">Exclusion Criteria</th></tr> </thead> <tbody> <tr> <td>Details</td><td> 1. History of systemic diseases (i.e. diabetes, autoimmune dysfunction, prolonged cortisone therapy, or chemotherapy) that would contraindicate periodontal surgical treatment. 2. Patients with deleterious habits like use of tobacco chewing or smoking. 3. History of previous periodontal surgical treatment. 4. Presence of malocclusion and pathologic movement of the teeth. 5. Presence of active carious lesions, restorations or crowns at the cemento-enamel junction (CEJ) as well as non-vital teeth with radicular grooves and irregularities. </td></tr> </tbody> </table>	Exclusion Criteria		Details	1. History of systemic diseases (i.e. diabetes, autoimmune dysfunction, prolonged cortisone therapy, or chemotherapy) that would contraindicate periodontal surgical treatment. 2. Patients with deleterious habits like use of tobacco chewing or smoking. 3. History of previous periodontal surgical treatment. 4. Presence of malocclusion and pathologic movement of the teeth. 5. Presence of active carious lesions, restorations or crowns at the cemento-enamel junction (CEJ) as well as non-vital teeth with radicular grooves and irregularities.
Exclusion Criteria					
Details	1. History of systemic diseases (i.e. diabetes, autoimmune dysfunction, prolonged cortisone therapy, or chemotherapy) that would contraindicate periodontal surgical treatment. 2. Patients with deleterious habits like use of tobacco chewing or smoking. 3. History of previous periodontal surgical treatment. 4. Presence of malocclusion and pathologic movement of the teeth. 5. Presence of active carious lesions, restorations or crowns at the cemento-enamel junction (CEJ) as well as non-vital teeth with radicular grooves and irregularities.				
Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc				
Method of Concealment	Sequentially numbered, sealed, opaque envelopes				
Blinding/Masking	Outcome Assessor Blinded				
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th><th>Timepoints</th></tr> </thead> <tbody> <tr> <td>Percentage of root coverage</td><td>1 month, 3 month, 6 month</td></tr> </tbody> </table>	Outcome	Timepoints	Percentage of root coverage	1 month, 3 month, 6 month
Outcome	Timepoints				
Percentage of root coverage	1 month, 3 month, 6 month				
Secondary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th><th>Timepoints</th></tr> </thead> <tbody> <tr> <td>Recession depth (RD), Recession width (RW), Relative attachment level (RAL), Width of keratinized tissue (WKT), Thickness of keratinised tissue (TKT)</td><td>1 month, 3 month, 6 month</td></tr> </tbody> </table>	Outcome	Timepoints	Recession depth (RD), Recession width (RW), Relative attachment level (RAL), Width of keratinized tissue (WKT), Thickness of keratinised tissue (TKT)	1 month, 3 month, 6 month
Outcome	Timepoints				
Recession depth (RD), Recession width (RW), Relative attachment level (RAL), Width of keratinized tissue (WKT), Thickness of keratinised tissue (TKT)	1 month, 3 month, 6 month				
Target Sample Size	Total Sample Size=20 Sample Size from India=20 Final Enrollment numbers achieved (Total)= Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)= Applicable only for Completed/Terminated trials				
Phase of Trial	N/A				
Date of First Enrollment (India)	01/07/2020				
Date of First Enrollment (Global)	No Date Specified				
Estimated Duration of Trial	Years=1 Months=0 Days=0				
Recruitment Status of Trial (Global)	Not Applicable				
Recruitment Status of Trial (India)	Not Yet Recruiting				
Publication Details	Nil				
Brief Summary	<p>This is a split mouth randomised single blinded clinical trial which is designed to evaluate the clinical efficacy of injectable platelet rich fibrin (i-PRF) with collagen membrane using minimally invasive VISTA technique with collagen membrane alone using the same technique for the treatment of Millers class 1 and class 2 gingival recessions in healthy subjects within age group of 18 yrs to 50 yrs. Here we are assessing the benefit of i-PRF with collagen membrane in improvement of recession coverage to collagen membrane alone.</p>				