



Clinical Trial Details (PDF Generation Date :- Sun, 28 Nov 2021 01:23:47 GMT)

<b>CTRI Number</b>	CTRI/2019/07/020320 [Registered on: 22/07/2019] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	13/05/2021	
<b>Post Graduate Thesis</b>	Yes	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Surgical/Anesthesia Diagnostic	
<b>Study Design</b>	Randomized, Parallel Group Trial	
<b>Public Title of Study</b>	To see the correlation between soft tissue graft with intact bony attachment versus free bone tendon bone (patellar tendon)graft with functional outcome after knee ligament (anterior cruciate) injury repair	
<b>Scientific Title of Study</b>	Correlation between ligamentization of two Anterior Cruciate Ligament grafts (Bone-Patellar Tendon-Bone vs Semitendinosus gracilis with preserved insertion) with functional outcome : A randomized control trial	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Govt Medical College and Hospital chandigarh			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	Govt Medical College and Hospital			
<b>Address</b>	sector 32B chandigarh			
<b>Type of Sponsor</b>	Government medical college			
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	Department of Science and Technology	Sector 19 Chandigarh		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
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<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	Institutional Ethics Committee (GMCH, Chandigarh)	Approved	31/12/2018	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Patients		Sprain of cruciate ligament of knee	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	ACL reconstruction surgery using BPTB graft and STGPI graft	All the patients will be divided into 2 groups by computer-generated random number sequence. In group I, ACL reconstruction will be done using BPTB graft and in group II, ACL reconstruction will be done using STGPI graft. 25 patients will be taken into STGPI group and 25 patients will be taken into BPTB group.	
	Comparator Agent	MRI, Knee laxity will be checked by anterior drawer test, Lachman test, knee arthropometer and pivot shift test, Tegner Lyshom knee surgery scoring scale, and	The patients will be regularly followed up and evaluated at 6 months and 1 year post surgery. Knee laxity will be checked by anterior drawer test, Lachman test, and pivot shift test at 6	



	Modified Cincinatti Rating scale.	months and 1 year. KT-1000 model knee arthropometer will be used, which will measure the anterior tibial motion relative to the femur both preoperatively and at various levels of follow up at 6 months, and 1 year. MRI will be done at 6 months and 1 year follow up to study the ligamentization of the ACL graft. Functional status of all the patients will be recorded using Tegner Lyshom knee surgery scoring scale, and Modified Cincinatti Rating scale.
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**Inclusion Criteria**

Inclusion Criteria	
<b>Age From</b>	18.00 Year(s)
<b>Age To</b>	40.00 Year(s)
<b>Gender</b>	Both
<b>Details</b>	1- Sports person 2- Age group- 18-40 years 3- Undergone primary ACL reconstruction with STGPI graft or BPTB graft. 4- Exclusive ACL tear

**Exclusion Criteria**

Exclusion Criteria	
<b>Details</b>	1- Revision ACL reconstruction 2- Undergone primary ACL reconstruction using STGF (Semitendinous-Gracilis Free) graft. 3- Previously operated on the same knee. 4- Infective pathology in the same knee. 5- Skeletally immature 6- Patient on steroids.

**Method of Generating Random Sequence**

Computer generated randomization

**Method of Concealment**

Not Applicable

**Blinding/Masking**

Not Applicable

**Primary Outcome**

Outcome	Timepoints
1. To study the correlation between rate and extent of ligamentization of two ACL grafts (STGPI vs BPTB) with functional outcome. 2. To compare the effect of two grafts (STGPI vs. BPTB graft) on functional outcome.	1 year and 6 months

**Secondary Outcome**

Outcome	Timepoints
1. To study the effect of type of graft (STGPI vs. BPTB graft) on timing of ligamentization.	1 year and 6 months

**Target Sample Size**

**Total Sample Size=50**  
**Sample Size from India=50**  
**Final Enrollment numbers achieved (Total)=0**  
**Final Enrollment numbers achieved (India)=50**

**Phase of Trial**

N/A

**Date of First Enrollment (India)**

22/07/2019

**Date of First**

No Date Specified



<b>Enrollment (Global)</b>	
<b>Estimated Duration of Trial</b>	<b>Years=1</b> <b>Months=6</b> <b>Days=0</b>
<b>Recruitment Status of Trial (Global)</b>	Not Applicable
<b>Recruitment Status of Trial (India)</b>	Completed
<b>Publication Details</b>	None
<b>Brief Summary</b>	<p>This study has main objectives, first is to analyse the ligamentization of the ACL grafts with MRI in patients who underwent ACL reconstruction with either BPTB graft or STGPI. And second is to find the correlation of the extent of Ligamentization to the functional outcome in the patients for both the grafts. In this study, we hypothesize the ligamentization in STGPI graft is comparable to BPTB graft and functional outcome is directly correlated with extent of ligamentization.</p>