



Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 10:02:46 GMT)

CTRI Number	CTRI/2019/07/020320 [Registered on: 22/07/2019] - Trial Registered Prospectively	
Last Modified On	13/05/2021	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Surgical/Anesthesia Diagnostic	
Study Design	Randomized, Parallel Group Trial	
Public Title of Study	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	
Scientific Title of Study	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	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Dr Ravi gupta
	Designation	Professor
	Affiliation	Government Medical College and Hospital
	Address	Department of Orthopaedics Government Medical College and Hospital, Sector 32 Chandigarh, India Chandigarh CHANDIGARH 160030 India
	Phone	9646121592
	Fax	
	Email	ravigupta2000@yahoo.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Sandeep Singh
	Designation	PG Resident
	Affiliation	Government Medical College and Hospital
	Address	Department of Orthopaedics Government Medical College and Hospital, Sector 32 Chandigarh, India Chandigarh CHANDIGARH 160030 India
	Phone	9653221300
	Fax	
	Email	mailsandy28@gmail.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr Sandeep Singh
	Designation	PG Resident
	Affiliation	Government Medical College and Hospital
	Address	Department of Orthopaedics Government Medical College and Hospital, Sector 32 Chandigarh, India Chandigarh CHANDIGARH



	160030 India									
Phone	9653221300									
Fax										
Email	mailsandy28@gmail.com									
Source of Monetary or Material Support	Source of Monetary or Material Support > Govt Medical College and Hospital chandigarh									
Primary Sponsor	Primary Sponsor Details									
	Name Govt Medical College and Hospital									
	Address sector 32B chandigarh									
	Type of Sponsor Government medical college									
Details of Secondary Sponsor	Name Department of Science and Technology Address Sector 19 Chandigarh									
Countries of Recruitment	List of Countries India									
Sites of Study	<table border="1"> <thead> <tr> <th>Name of Principal Investigator</th> <th>Name of Site</th> <th>Site Address</th> <th>Phone/Fax/Email</th> </tr> </thead> <tbody> <tr> <td>Dr Sandeep Singh</td> <td>Government Medical College and Hospital, Chandigarh</td> <td>Room No. 3208 B block Orthopaedic Surgery OPD, Government Medical College and Hospital, Sector 32 Chandigarh, India CHANDIGARH</td> <td>9653221300 mailsandy28@gmail.com</td> </tr> </tbody> </table>	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email	Dr Sandeep Singh	Government Medical College and Hospital, Chandigarh	Room No. 3208 B block Orthopaedic Surgery OPD, Government Medical College and Hospital, Sector 32 Chandigarh, India CHANDIGARH	9653221300 mailsandy28@gmail.com	
Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email							
Dr Sandeep Singh	Government Medical College and Hospital, Chandigarh	Room No. 3208 B block Orthopaedic Surgery OPD, Government Medical College and Hospital, Sector 32 Chandigarh, India CHANDIGARH	9653221300 mailsandy28@gmail.com							
Details of Ethics Committee	<table border="1"> <thead> <tr> <th>Name of Committee</th> <th>Approval Status</th> <th>Date of Approval</th> <th>Is Independent Ethics Committee?</th> </tr> </thead> <tbody> <tr> <td>Institutional Ethics Committee (GMCH, Chandigarh)</td> <td>Approved</td> <td>31/12/2018</td> <td>No</td> </tr> </tbody> </table>	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?	Institutional Ethics Committee (GMCH, Chandigarh)	Approved	31/12/2018	No	
Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?							
Institutional Ethics Committee (GMCH, Chandigarh)	Approved	31/12/2018	No							
Regulatory Clearance Status from DCGI	<table border="1"> <thead> <tr> <th>Status</th> <th>Date</th> </tr> </thead> <tbody> <tr> <td>Not Applicable</td> <td>No Date Specified</td> </tr> </tbody> </table>	Status	Date	Not Applicable	No Date Specified					
Status	Date									
Not Applicable	No Date Specified									
Health Condition / Problems Studied	<table border="1"> <thead> <tr> <th>Health Type</th> <th>Condition</th> </tr> </thead> <tbody> <tr> <td>Patients</td> <td>Sprain of cruciate ligament of knee</td> </tr> </tbody> </table>	Health Type	Condition	Patients	Sprain of cruciate ligament of knee					
Health Type	Condition									
Patients	Sprain of cruciate ligament of knee									
Intervention / Comparator Agent	<table border="1"> <thead> <tr> <th>Type</th> <th>Name</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Intervention</td> <td>ACL reconstruction surgery using BPTB graft and STGPI graft</td> <td>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.</td> </tr> <tr> <td>Comparator Agent</td> <td>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</td> <td>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</td> </tr> </tbody> </table>	Type	Name	Details	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
Type	Name	Details								
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.
--	-----------------------------------	---

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	40.00 Year(s)
Gender	Both
Details	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	
Details	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



Enrollment (Global)	
Estimated Duration of Trial	Years=1 Months=6 Days=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	None
Brief Summary	<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>