

INFORMED CONSENT

Functional Outcome Comparison of Implantless Bone-Patellar Tendon Autografts Using Press-Fit Fixation
Technique and Hamstring Autografts Using Implant in Arthroscopic Anterior Cruciate Ligament
Reconstruction: A Prospective Study

NCT number: not yet registered

March 1, 2013



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Med. Rec. No. :
Name :
Gender :
Birth date :

(or please put sticker I.D.)

INFORMED CONSENT FORM FOR INTERVENTIONAL STUDY

Principal Investigator	Andri Maruli Tua Lubis, M.D., Ph.D
Information provider	
Information recipient	
Name of the subject	
Birth date	
Gender	
Address	
Phone number	

NO	JENIS INFORMASI	ISI INFORMASI	CHECK
1.	Study title	Functional Outcome Comparison of Implantless Bone-Patellar Tendon Autografts Using Press-Fit Fixation Technique and Hamstring Autografts Using Implant in Arthroscopic Anterior Cruciate Ligament Reconstruction: A Prospective Study.	
2.	Study purpose	To find whether implantless ACL reconstruction gave comparable functional outcome objectively and subjectively compared to the ACL reconstruction using implant technique	
3.	Study method	Experimental descriptive	
4.	Risks and side effects	Pain, infection, joint stiffness, complications related to anesthesia procedure	
5.	Benefit of the study	Obtain the information regarding the functional outcome on ACL reconstruction using implantless technique	
6.	Procedures	Diagnosis of ACL rupture was done by physical examination using Lachman Test, Anterior Drawer Sign Test, and Pivot Test on both knee. Another test was also performed to exclude another knee ligament rupture, such as Posterior Drawer Test, Varus & Valgus Test. MRI was obtained to make an accurate diagnosis for ACL rupture using 3 projections, which were coronal, sagittal, and axial, each on T1 and T2 weighted image. After the diagnosis was confirmed, the subject underwent a surgery performed by single same operator in Sports Injury Division of Orthopaedic Department in Gatot Soebroto Army Hospital. Result for functional outcome objectively was obtained by using a Rollimeter when doing a Lachman Test. It was performed at preoperation and 6 months postoperation. For subjective functional outcome, was obtained by IKDC Subjective Knee Evaluation Form (IKDC), Tegner Lysholm Knee Scoring Scale (Tegner) and Knee Injury and Osteoarthritis Outcome (KOOS). It was performed at	



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	preoperation, 1 month, 3 months and 6 months postoperation.
7. Potential discomfort	Post-operative pain, bleeding, and stiffness.
8. Alternative study	Not available
9. Data confidentiality	As with any medical record file, all research data will be treated confidentially so as not to allow others to associate it with patients (research subjects).
10. Study compensation	Not available
11. Investigator contact	Andri Maruli Tua Lubis, M.D., Ph.D Phone: +628161177078
12. Target number of subject	60 subjects
13. Potential danger	Complications related to surgery and anesthesia procedure
14. Funding	Self-funded
15. Incentive for subject	Not available

After obtaining explanations on pages 1 to 2 regarding the research of Andri Maruli Tua Lubis, M.D., Ph.D, entitled "Functional Outcome Comparison of Implantless Bone-Patellar Tendon Autografts Using Press-Fit Fixation Technique and Hamstring Autografts Using Implant in Arthroscopic Anterior Cruciate Ligament Reconstruction: A Prospective Study", I have understood that information very well.

By signing this form, I agree to be included in the above research voluntarily without coercion from any party. If at any time I feel disadvantaged in any form, I have the right to cancel this agreement.

Signature of the subject (Name of the subject)	Date:
Signature of the witness (Name of the witness)	Date:
Signature of the study investigator (Name of the investigator)	Date: