



Stability II Trial

Recruiting young active ACL-deficient patients at high risk of ACL re-injury

Sponsored by: National Institute of Arthritis Musculoskeletal and Skin & Canadian Institutes of Health Research
Canadian Institutes of Health Research

Anterior cruciate ligament (ACL) reconstruction surgery has unacceptably high failure rates in young active individuals. ACL graft choice and/or augmentation with a lateral extra-articular tenodesis (LET) has the potential to reduce failure rates in this patient population.

This international, multicentre randomized clinical trial will determine if ACLR using a patient's own quadriceps tendon or patellar tendon, either with or without a LET, reduces the risk of ACL failure, results in less symptoms, better function and quality of life, and an improved ability to return to sports. It is anticipated that 1,236 people will participate from research sites in Canada, the United States, Germany, Norway, the United Kingdom and Sweden.

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> <input type="checkbox"/> ACL-deficient knee <input type="checkbox"/> Ages 14 – 25 years <input type="checkbox"/> Skeletally mature <input type="checkbox"/> 2 of the following: <ul style="list-style-type: none"> <input type="checkbox"/> Competes in a competitive pivoting sport <input type="checkbox"/> Has generalized ligamentous laxity (≥ 4 Beighton score) <input type="checkbox"/> Grade 2 pivot shift <input type="checkbox"/> Genu recurvatum of >10 degrees 	<ul style="list-style-type: none"> <input type="checkbox"/> Previous ACL reconstruction of either knee <input type="checkbox"/> Multiple ligament injury (ie: PCL, collaterals) requiring repair / reconstruction <input type="checkbox"/> Symptomatic articular cartilage defect <input type="checkbox"/> Inflammatory arthritis, metabolic bone, collagen, crystalline, degenerative joint or neoplastic disease <input type="checkbox"/> Femoral, tibial or patellar fracture (other than Segment fractures) <input type="checkbox"/> Asymmetric valgus or varus > 3 degrees <input type="checkbox"/> Debilitating anterior knee pain, patellar or quadriceps tendon tendonitis

What is Involved?

1. Clinical study visits at the Fowler Kennedy Sport Medicine Clinic for 2 years of follow-up
2. Standardized knee examinations, knee x-rays and completion of online questionnaires
3. Muscle strength tests, and hop and jump tests to measure function levels
4. Patient is randomized in the operating room to one of four groups:
 - Quadriceps tendon with a lateral extra-articular tenodesis
 - Quadriceps tendon without a lateral extra-articular tenodesis
 - Patellar tendon with a lateral extra-articular tenodesis
 - Patellar tendon without a lateral extra-articular tenodesis

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