L-C LIGAMENT® VERSUS HAMSTRING AUTOGRAFT FOR PRIMARY ACL RECONSTRUCTION: A PROSPECTIVE, RANDOMIZED CONTROLLED TRIAL

Published: 12-09-2017
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To assess performance and safety of L-C Ligament® against autograft surgery with hamstring tendon for primary ACL reconstruction.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON53337

Source
ToetsingOnline

Brief title
RCT

Condition

- Tendon, ligament and cartilage disorders

Synonym
ruptured anterior cruciate ligament

Research involving
Human

Sponsors and support

Primary sponsor: Biorez Inc.
Source(s) of monetary or material Support: Biorez Inc.

Intervention

Keyword: ACL reconstruction, Anterior cruciate ligament (ACL), Randomised, Synthetic device

Outcome measures

Primary outcome

Safety:

The primary safety endpoint is defined as absence of revision surgery for graft

failure. A subject is a responder (success) if at 12 months post-procedure the

patient has not undergone revision surgery due to graft failure (tear/rupture,

loss of fixation, infection, etc).

Performance:

The primary performance endpoint is based on IKDC Subjective Evaluation scores.

A subject is a responder (success) if at 12 months post-procedure the patient

has an overall IKDC Subjective Evaluation score improvement of * 12 points over

baseline.

Secondary outcome

SECONDARY ENDPOINTS:

The following variables will be characterized for both groups:

* Numeric Pain Scores at Day 1 post-procedure

* AE/SAE rates at all follow-up time points

ADDITIONAL ANALYSES:

The following will also be reported at available study timepoints:

* Subjective outcomes (Lysholm score, Tegner Score, KOOS Score)

* Clinical outcomes (Lachman, Anterior drawer, Pivot-shift, single-leg hop

test)

* Instrumented testing outcomes (KT1000)

* MRI outcomes

* Other Imaging outcomes (CT, X-Ray)

* Health Economics (Procedure time, hospitalization duration, complication

rates, medications, recovery duration, time to return to work, quality of life,

etc)

Study description

Background summary

The anterior cruciate ligament (ACL) is one of the most important ligaments of the knee. Along with the other knee ligaments, the two menisci, cartilage and muscl,e the anterior cruciate ligament ensures the stability of the knee joint. The stability is necessary for the proper functioning of the knee in everyday life and during the performance of sports. The anterior cruciate ligament ensures that the lower leg relative to the upper leg is prevented from sliding too far and cannot rotate too far. A damaged ligament is usually perceived as "going through the knee" and is often accompanied by a snapping sound. Usually the knee will swell.
In this study we want to investigate the performance and safety of L-C Ligament on long term (5 years). In addition, the study will compare performance and safety profiles for the two groups (comparator being autograft surgery with hamstring tendon).
The LC ligament is a three-dimensional (3-D) braided support made of a fiber (PLLA), a material that is resorbed by the body. The PLLA material whose LC ligament is made, has a long and successful history (over 15 years) as a biological material in many implants for orthopedic and sports medicine use.

Study objective

To assess performance and safety of L-C Ligament® against autograft surgery with hamstring tendon for primary ACL reconstruction.

Study design

This is a multicenter, randomised clinical investigation that will be performed in maximum 6 centers. 60 (2:1 - L-C ligament vs autograft) patients will be included. The study will last 5 years for the patients.

Intervention

ACL reconstruction with the L-C ligament or autograft.

Study burden and risks

An arthroscopy is a very safe procedure during which complications occur only rarely. The possible complications include: severe and long-term swelling, bleeding in the knee, damage to nerves in the skin, and, very rarely, inflammation of the joint. These risks are also present for every other type of reconstruction to the anterior cruciate ligament.

Adverse effects associated with general anaesthesia include: drowsiness, nausea, sore throat and hoarseness. Rare complications include: hypersensitivity reactions to the medications administered during the procedure and injury to the nerves.

As L-C Ligament is an experimental device, some of the risks associated with it are not yet known. Possible risks associated with the L-C Ligament device include, but are not limited to:
The known risks are listed below
* Allergic reaction to device / materials
* Pain or discomfort caused by device failure
* Inflammation
* Instability in your knee caused by device failure
* Infection caused by reaction to the device
* Persistent effusion
* Cyst formation
* Premature uptake by the body
* Delay in recovery and/or abnormal healing of your ACL

The risks of autograft surgery with your hamstring tendon include, but are not limited to:
* Weakness and/or loss of endurance of the hamstring muscles
* Pain in the back of your knee

* Infection
* Instability in your knee
* Vascular Injury
* Hematoma (collection of blood outside the blood vessels)
* Chronic hamstring strain with pain
* If your harvested hamstring is too short, then your patella tendon might be harvested

Anticipated risks associated with any ACL reconstruction procedure not specific to the L-C Ligament or hamstring autograft include, but are not limited to:
* Allergic reaction to medication
* Bone fracture
* Cyclops lesion
* Deep vein thrombosis (blood clot in your legs)
* Effusion (Excess fluid build-up)
* Graft failure
* Hardware removal
* Hematoma (collection of blood outside the blood vessels)
* Infection
* Instability in your knee
* Nerve Injury
* Pain
* Pulmonary Embolism
* Soft Tissue Injury
* Stiffness in the joints
* Swelling / bruising
* Vascular Injury

The amount of radiation to which you will be exposed will normally not differ from that of other endoscopic procedures, and should therefore not place the subject at any increased risk.

Pregnant women will be excluded from participation in this study. This restriction applies to the entire study period. Women of childbearing potential should therefore take reliable measures to prevent getting pregnant during the study.

Benefits
There is no guarantee that you will benefit from participating in the study The study treatment may lead to improvement or no improvement, or the condition may worsen. It is expected that the reconstruction operation of the anterior cruciate ligamentwill reduce the pain , and improves the functioning of the knee joint.

It is thanks to this type of research that better treatments for torn anterior cruciate ligament can be developed.

Contacts

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Trial sites

Listed location countries

Austria, Germany, Hungary, Ireland, Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Signed Informed Consent
* 18 to 45 years of age
* Closed tibial and femoral physes
* If female, for the 24 months post-operative, actively practicing a contraception method, or surgically sterilised or postmenopausal
* Acute unilateral ACL tear, or partial or complete tear of the ACL, that requires reconstruction of the ACL. Reconstruction surgery must occur within 18 weeks (126 days) of injury

* Passive flexion * 120° and passive extension on the target knee is the same as the contralateral knee
* If a concomitant Medial Collateral Ligament (MCL) injury is present: grade 2 or less
* Baseline IKDC Subjective Evaluation score * 70
* Willing to not participate in sports for a minimum of 9 months post-procedure
* Physically and mentally willing and able to comply with post-operative rehabilitation and routinely scheduled clinical, radiographic and rehabilitation follow up visits through 60 months.

Exclusion criteria

* Prior ACL reconstruction or other surgical procedure on the affected (target) ACL
* Chronic ACL injury; interventional surgery scheduled 127 days or more after ACL injury
* Professional athletes currently engaged in active sport
* Baseline Tegner score *9
* Prior distal femoral and/or proximal tibial fracture(s) of the target leg
* Previous or current ACL injury on contra-lateral leg
* Multi-ligament reconstruction
* Malalignment or varus thrust
* Patient > 193 cm tall (6* 4*)
* Confirmed connective tissue disorder
* Signs of moderate to severe degenerative joint disease (such as osteoarthritis), including ICRS Score of 3 or 4
* Presence of cartilage defects that requires a surgical intervention other than microfracture technique
* Severe pain, swelling, or redness within 24 hours prior to surgery
* Complete or partial Post Cruciate Ligament (PCL) tear
* If a concomitant meniscal tear is present, any of the following: (a) the meniscal tear is not repairable in the clinical judgement of the Investigator; (b) *1/3 meniscal resection required; (c) complex double-bucket tear; (d) previously partially repaired tears; (d) previously partially repaired tears; (e) other meniscus injury that may negatively impact the function of the ACL
* Additional concomitant injuries to the knee or lower extremities requiring treatment, per surgeon's discretion, that are not allowable under the Inclusion criteria
* The patient is mentally compromised
* The patient has a neuromuscular disorder that would endanger unacceptable risk of knee instability, prosthesis fixation failure, or complications in postoperative care
* The patient has an active or latent infection in or about the affected knee joint or an infection site distant from the knee that may spread to the knee hematogenously
* Pregnant (based on a positive beta hCG serum or an in vitro diagnostic test result) or breast-feeding
* The patient is obese with a BMI * 35
* The patient has a known allergy to PLLA
* The patient has a medical condition, including metabolic bone disease (e.g., osteoporosis or rickets), crystal deposition disease (e.g., gout), inflammatory joint disease (e.g., rheumatoid arthritis), known neoplastic disease, or comorbidity that would interfere with study

participation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	L-C ligament
Registration:	No

Ethics review

Approved WMO Date:	02-06-2015
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-08-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO Date:	12-10-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Not available Date:	22-03-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	17-01-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	12-09-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02183727
CCMO	NL49825.075.14