A Prospective and Consecutive Clinical Evaluation of Soft Tissue Regeneration*s L-C Ligament® in Primary ACL Reconstruction

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

Summary

ID

NL-OMON53168

Source
ToetsingOnline

Brief title
L-C Ligament

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), Synthetic device

Outcome measures

Primary outcome

* Absence of graft failure (attributed to the device) at one year

* Absence of revision ACL surgery at one year post-procedure

required due to any of the following:

* Tear or rupture in the graft

* Serious infection attributed to the L-C Ligament

* Substantial laxity attributed to loss of fixation in the femoral

or tibial tunnels directly attributed to the L-C Ligament

Secondary outcome

The following variables will be analyzed for informational purposes:

- Clinical function as assessed by the 2000 IKDC scale at pre-op, post-op, 3,

6, 12, 18 and 24 months.

- Safety rates per intra- and post- operative complications.

- KOOS Pain, Tegner and Lysholm scores pre-op, post-op, 3, 6, 12, 18 and 24

months and 3 ,4 and 5 years.

- Radiographic, MRI, and CT assessment of the position of the femoral & tibial

tunnels, indirect evidence of ligament tissue remodeling, and evidence of

tunnel-widening.

- Clinical function measured with the Lachman, anterior drawer, KT1000*,

pivot-shift, and single-leg hop tests at pre-op, 6, 12, 18 and 24 months (and

optionally at Years 3, 4, and 5).

Study description

Background summary

Injury of the anterior cruciate ligament (ACL) is a common occurrence in the young adult population. An estimated 250.000 ACL reconstructions are performed annually in the USA with more than 300.000 in the developed international market. The incidence of this injury is roughly 1 in 3000 per year. ACL injury has immediate and long-term consequences, which include increased risk for osteoarthritis and long-term disability.
The ACL has poor healing potential. Chronic tears and ruptures are usually treated with autograft or allograft.
The design of the L-C Ligament is intended to eliminate the morbidity associated with autograft, negates the risk of disease transmission and variability in quality associated with allograft, and should provide similar or improved healing and clinical function compared to allo- and auto- graft tissues. The objective of this investigation is to evaluate safety, pre- and post-operative pain, and clinical function of the L-C Ligament.

Study objective

The primary objective of this study is to evaluate the safety of the L-C Ligament in primary ACL reconstruction.
The secondary objectives of this study are to evaluate pain, function, and radiographic performance of the L-C Ligament in primary ACL reconstruction.

Study design

This is a multicenter clinical investigation that will be performed in maximum 3 centers. 15
patients will be included. The study will last 5 years for the patients.

Intervention

ACL reconstruction with the L-C ligament.

Study burden and risks

Every medical procedure carries risks with it. Since the LC ligament an investigational medical device , some risks are unknown.

An arthroscopy is a very safe procedure with rare complications. Possible complications include: sharp and prolonged swelling, bleeding in the knee, damaged skin nerve, and very rarely arthritis. These risks are similar to any other reconstruction procedure of the anterior cruciate ligament.

Side effects of general anesthesia may include: drowsiness, nausea, sore throat / or hoarseness. Rare complications include: hypersensitivity reactions to the drugs used during anesthesia and nerve injury.

Potential risks associated with the use of this medical device, which we do not expect to occur, include: loosening, failure of fixation failure or wear, premature or delayed resorption by the body, delayed healing and / or abnormal recovery from your ACL. These risks are similar to other treatment options for reconstruction of the anterior cruciate ligament, such as the use of allogeneic and autogenous tissue.

The amount of X-rays which one is exposed to, is normally not greater than during keyhole surgery procedures and would not increase the risk.

Pregnant women are excluded from this study. This applies to the entire study. Women of childbearing age should therefore take proper measures to avoid becoming pregnant during the study. The doctor will discuss with the subject, before they consent to participate in the study, the most appropriate contraceptive measures . If the subject, despite all precautions, does become pregnant during the study, she will be asked to contact the investigator / treating doctor immediately. It is not known what the consequences of participation in the study for the unborn child are.

Benefits
It is expected that the reconstruction of the anterior cruciate ligament surgery ensures that the pain decreases, and enhances the functioning of the knee joint. However, it is possible that the subject does not experience benefits.
It is thanks to this type of research that better treatments for torn anterior cruciate ligament can be developed.

Contacts

Public
Biorez, Inc.

Church Street, 17th Floor 195
New Haven Suite 206
US

Scientific
Biorez, Inc.

Church Street, 17th Floor 195
New Haven Suite 206
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

18 to 45 years of age.
Males and females.
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 occurred within 91 days (13 weeks) of injury, and requires reconstruction of the ACL.
Passive flexion - 120° and passive extension on the target knee is the same as the contralateral knee.
Patients with all types of lateral and/or medial meniscal tears which are repairable.
Medial Collateral Ligament (MCL) grade 2 or less.
Potential Subject is able to provide informed consent and must sign the EC-approved Informed Consent Form
Must be physically and mentally willing and able to comply with post-operative rehabilitation and routinely scheduled clinical, radiographic and rehabilitation follow up visits through 24 months.

Exclusion criteria

Prior ACL reconstruction or other surgical procedure on the affected (target) knee.
Chronic ACL injury; interventional surgery scheduled 92 days or more after ACL injury.
Professional athletes currently engaged in active sport
Prior fracture of the affected (target) leg
Previous or current ACL injury on contra-lateral leg.
Multi-ligament reconstruction.
Malalignment with varus thrust
Patient > 193 cm tall (6* 4*).
The patient does not follow pre-operative rehabilitation.
Confirmed connective tissue disorder.
Signs of moderate to severe degenerative joint disease (Osteoarthritis)
Concomitant injuries to the knee or lower extremities requiring treatment, per surgeon's discretion.
Severe pain, swelling, or redness within 24 hours prior to surgery.
Complete or partial Post Cruciate Ligament (PCL) tear.
Any of the following: 1/3rd meniscal resection; complex doublebucket tear; partially repaired meniscal tears.
Patient requires treatment of articular cartilage on target leg
The patient is mentally compromised.
The patient has a neuromuscular disorder that would engender unacceptable risk of knee instability, prosthesis fixation failure, or complications in postoperative care.
The patient has a diagnosed systemic disease that would affect his/her safety or the study outcome.
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 ³ 35.
The patient has a known allergy to PLLA.
The patient has a medical condition or comorbidity that would interfere with study participation.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-06-2013
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	L-C Ligament
Registration:	No

Ethics review

Approved WMO

Date:	18-12-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO

Date:	18-02-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO

Date:	15-04-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO

Date:	14-05-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO Date:	03-06-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	01-08-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	09-09-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	15-10-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	19-12-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-04-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	19-08-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-10-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	02-06-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	

Date:	22-09-2017
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	NCT01634711
CCMO	NL41298.075.12