Dynamic Intraligamentairy Stabilisation of the acute torn anterior cruciate ligament, a multicenter prospective cohort study.

Published: 06-04-2015
Last updated: 21-04-2024

To assess the efficacy of treatment of acute ACL ruptures with the Ligamys device.

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

Summary

ID

NL-OMON47627

Source
ToetsingOnline

Brief title
Ligamys Trial

Condition

- Tendon, ligament and cartilage disorders

Synonym
ACL rupture, Rupture Cruciate Ligament

Research involving
Human

Sponsors and support

Primary sponsor: Xpert Orthopedie
Source(s) of monetary or material Support: Mathys Medical en SKWOSZ,Mathys Medical Ltd

Intervention

Keyword: ACL, Repair, Rupture

Outcome measures

Primary outcome

Our primaire endpoint is the stability compared to the contralateral leg measured by a KT1000 test will be performed. This non invasive test provides an objective assessment of the amount of increased anterior knee translation between 20 and 30 degrees of knee flexion.

Secondary outcome

Our secondary endpoints are the Tegner, IKDC, NRS pain and NRS instability scores. These are knee specific questionnaires specifically designed to measure outcome after knee surgery.

Study description

Background summary

In the last decades ACL reconstruction has become widely accepted as a valid option in the treatment for chronic ACL rupture. In case of an acute ACL rupture there have been several treatment options mentioned in recent history. One of these options is the Ligamys device. The Ligamys is a CE certified device to repair and internally brace an acute ACL rupture.

Study objective

To assess the efficacy of treatment of acute ACL ruptures with the Ligamys device.

Study design

The study design is a prospective case serie assessing the clinical outcome, range of motion and objective stability after treatment of acute ACL rupture with the Ligamys device. Inclusion will start in 2015, with a maximum follow up

of 5 years per patient. The study will be conducted in the Haga Hospital, Annatommie, Amstelland hospital and Slotervaart Hospital.

Study burden and risks

All patient will be seen at regular follow up intervals identical to the normal ACL reconstruction follow up.
All patients will be treated according to standard ACL protocol, with an implant that is available on the market and has a CE marking. Bearing this in mind we judge the study as safe.
The extra burden for these patients will be the questionnaires required at each follow up, requiring a total of 15 minutes per questionnaire. Additionally a scheduled follow up visit at one year follow up contains an extra measurement with the KT-1000 to measure stability of the ACL, this is a non-invasive testing which is performed in 10 minutes.
The 2 and 5 year follow up will be performed with an online form.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Acute primary rupture of the anterior cruciate ligament
* Signed patient informed consent
* Willingness to present for follow-up
* Age between 18 and 50 years at the time of inclusion in the study
* Injury - surgery time interval of 21 days or less
* BMI <35
* Tegner score 6 or more

Exclusion criteria

* Co-morbidity influencing the outcome of the implant.
* Hypersensetivity to metals.
* Not being able to fill in the Dutch Questionnaires.
* Osteo arthritis Kelgren grade 2 or more on conventional x-ray
* Medical non-compliance
* Unwillingness to follow the rehabilitation programme
* Traumatic cartilage lesion requiring cartilage repair procedure (Microfracturing, MACI, ACT) or degenerative cartilage lesions (Outerbridge >II and defect >1cm2)
* Non-repairable meniscus lesions requiring a resection of >20%
* Previous tendon removal on injured leg
* Relevant permanent medication (Steroids, cytostatic drugs, ...)
* Pregnancy
* Reumatoid arthritis
* Instability of the contralateral leg

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2015
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL51958.048.14

Study results

Date completed:	24-08-2020
Actual enrolment:	150