

Measurements for a safe return to sports after ACL reconstruction.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON19946

Source

NTR

Brief title

N/A

Health condition

Anterior cruciate ligament reconstruction (ACLR)Voorste kruisband (VKB) reconstructie
Anterior cruciate ligament rupture
Voorste kruisband ruptuur

Sponsors and support

Primary sponsor: Sport Medisch Centrum Papendal, Arnhem
Universitair Medisch Centrum St Radboud, IQ healthcare, Nijmegen
Rijnstate Ziekenhuis, Arnhem
Kliniek ViaSana, Mill

Source(s) of monetary or material Support: Fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

- Number of graft reruptures and contralateral ACL ruptures two years after ACLR, comparison between subgroups based on limb symmetry index score or qualitative performance.
- Number of injuries at lower limb two years after ACLR, comparison between subgroups based on limb symmetry index score or qualitative performance.

Secondary outcome

- Number of athletes that returned to preinjury sport level two years after ACLR, comparison between subgroups based on limb symmetry index score or qualitative performance.
- Duration of rehabilitation related to preoperative scores.

Study description

Background summary

For athletes rehabilitation after anterior cruciate ligament reconstruction (ACLR) could be judged successful if they return to their previous level of sports. Recent research, however, shows that one third of athletes does not return to this sport level within two years. After three or more years this number even increases to 50%. Half of these athletes report their ACL injury as the primary reason for a lower activity level. Moreover, athletes that do return to their previous sport level have a considerable risk of tearing the graft or the contralateral ACL within the first two years; 3-22% of athletes rerupture the reconstructed ligament and 3-24% rupture the contralateral ACL. The risk of a contralateral ACL injury is higher when returning to a high level of pivoting sports. Three recent systematic reviews show that most clinicians do not use objective criteria for determining the moment of return to sports. Furthermore, there are no measurements for quality of movement performed, despite previous studies showed that, besides quantity, also quality of movement can be a causal factor for ACL (re)ruptures. The presence of dynamic knee valgus when landing from a jump and deficits in neuromuscular control of the trunk can predict ACL injury in healthy athletes. Also, the occurrence of dynamic knee valgus and a smaller knee flexion angle during landing are predictive for ACL rerupture. It can be concluded that both components of functional performance are important in rehabilitation after ACLR and prevention of (re)injuries. Nevertheless, there has never been conducted a prospective cohort study with ACLR athletes, to investigate whether an extensive test battery for measuring quantity and quality of movement is able to predict safe return to sports.

Study objective

The aim of this study is to correlate the score on a functional performance test battery to the occurrence of ACL reruptures and contralateral ruptures. We hypothesize that athletes with a limb symmetry index of <100% on strength or hop tests or a bad quality of movement have

more risk for graft rerupture or contralateral rupture.

Study design

Measurements are conducted at the following timepoints:

T0 – preoperative

T1 – at the end of the first postoperative phase

T2 – at the end of the second postoperative phase

T3 – at the end of the third postoperative phase

T4 – 1 year postoperative

T5 – 1 year and 3 months postoperative

T6 – 1 year and 6 months postoperative

T7 – 1 year and 9 months postoperative

T8 – 2 years postoperative

Intervention

The rehabilitation after ACLR will follow the KNGF Evidence Statement (that will be published in the fall of 2013). Measurement of functional performance are according to the Evidence Statement. The measurements include both quantity and quality of functional performance: strength measurements, hop test battery, video-analysis for quality of movement during drop jump. Before surgery and after finishing rehabilitation, only an online questionnaire is send, with questions about return to sports and injuries.

Contacts

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Eligibility criteria

Inclusion criteria

- ACLR from September 2013 until December 2014
- 16-40 years old, male and female
- Athletes with preoperative Tegner Activity scale ≥ 6 (only pivoting sports)
- Any arthroscopic surgical method for ACLR with bone-patellar tendon-bone or semitendinosus/gracilis autograft
- All fixation methods
- Concomitant ligament injury (MCL, LCL, PCL, posterolateral corner) grade A or B (IKDC criteria)
- Concomitant meniscectomy
- Cartilage pathology grade I or II (ICRS criteria)
- Patient is willing to rehabilitate at a physiotherapy practice that is a member of the hospitals network
- Patients willing to sign informed consent

Exclusion criteria

- Autograft or synthetic graft
- Revision surgery
- Meniscal repair
- Concomitant ligament injury C or D

- Cartilage pathology grade III or IV

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2014
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion	
Date:	20-08-2013
Application type:	First submission

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
NTR-new	NL3845
NTR-old	NTR4130
Other	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Intention of publication of study protocol within one year time and of study results after the study is finished.