

Measurements for a safe return to sports after ACL reconstruction.

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON19946

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

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

Ondersteuning

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

Overige ondersteuning: Fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

The aim of this study is to correlate the score on a functional performance test battery to the occurrence of ACL ruptures 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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ACLR from September 2013 untill 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Autograft or synthetic graft
- Revision surgery
- Meniscal repair

- Concomitant ligament injury C of D
- Cartilage pathology grade III or IV

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2014
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	20-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3845
NTR-old	NTR4130
Ander register	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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