Repair versus reconstruction of proximal anterior cruciate ligament tears

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Patients undergoing ACL repair have non-inferior primary and secondary outcomes when compared to the current gold standard of ACL reconstruction

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22748

Bron
Nationaal Trial Register

Verkorte titel
REPAIR

Aandoening

Complete tear of the anterior cruciate ligament

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Dutch Association of Arthroscopy

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Subjective International Knee Documentation Comitee (IKDC) score at two-year follow-up

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: For active patients with a tear of the anterior cruciate ligament (ACL) who would like to return to active level of sports, the current gold surgical standard is reconstruction of the torn ligament (removal of torn ligament and replacement by a tendon graft). Recently, there has been renewed interest in repairing the torn ligament in selected group of patients (those with a tear in the proximal part of the ligament). Repair of the ligament has some theoretical advantages over reconstruction of the ligament such as decreased surgical morbidity, faster return of range of motion, and potentially a decreased awareness of the knee. Studies comparing both treatments in a prospective randomized study are, however, lacking.

Objective: The main objective is to compare the subjective and objective outcomes following repair and reconstruction for patients with acute proximal copmlete ACL tears at two-year follow-up

Hypothesis: The hypothesis is that ACL repair is non-inferior to the current gold standard of ACL reconstruction

Study design: Prospective multicenter randomized controlled study

Study population: All patients aged 18 – 50 with an ACL tear in the proximal part of the ligament and the desire to return to sports. A total of 74 patients will be randomized into two equal groups of 37 patients.

Intervention: One group will undergo repair of the proximally torn ACL whereas the other group will undergo standard reconstruction.

Main study parameters/endpoints: The primary study parameter is the subjective IKDC score that indicates the subjective outcomes reported by the patient, at two-year follow-up. Secondary outcomes are other patient-reported outcome measures, objective outcomes (e.g. failure, objective assessment, stability), and return to sports rate and patients will be followed until 2 years after surgery.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will undergo rehabilitation protocol which is standard for ACL surgery and patients will fill in questionnaires and answer questions at 3 months, 6 months, 9 months, 1 year and 2 years after surgery. No additional risk for patients is expected beyond the normal risk for arthroscopic ACL surgery.

Doel van het onderzoek

Patients undergoing ACL repair have non-inferior primary and secondary outcomes when compared to the current gold standard of ACL reconstruction

Onderzoeksopzet

Baseline, treatment, 3 months postoperatively, 6 months postoperatively, 9 months postoperatively, 12 months postoperatively and 24 months postoperatively

Onderzoeksproduct en/of interventie

Patients with proximal ACL tears will be randomized into two treatment arms:
1. ACL repair (intervention): the torn ACL will be repaired and fixated back to the femoral origin using sutures and a cortical button and the repaired ligament will be reinforced using an internal suture augmentation
2. ACL reconstruction (gold standard; control): the torn ACL will be removed and replaced by a graft from the semitendinosus and gracilis tendons using all-inside drilling and cortical button fixation

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Preoperatively:
- Complete primary anterior cruciate ligament injury on physical examination and MRI
- Tear in proximal quarter on MRI
- Age 18 - 50

- Preinjury Tegner activity level ≥5 and desired Tegner activity level ≥5 (otherwise they can be treated non-operatively)
- Operation within 4 weeks of injury

Intraoperatively:
- Sufficient tissue length (proximal tear that can be reattached to insertion site)
- Sufficient tissue quality (to withhold repair sutures)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Preoperatively:
- Complete ipsilateral concomitant knee ligament injury requiring surgery
- Concomitant ipsilateral knee dislocation or patellar dislocation
- Osteoarthritis KL grade ≥2
- Previous ipsilateral ACL reconstruction/repair
- Intra-articular corticosteroids 6 months prior
- No understanding of Dutch language or not capable of understanding the study and participation
- No preoperative flexion of 90 degrees
- Grade 3 pivot shift indicating gross ligament instability that requires additional proce-dures
- Gross lower leg malalignment requiring bony osteotomies
- Muscular, neurological or vascular diseases that influence rehabilitation or surgery
- Prolonged use medication use of prednison or cytostatics
- Pregnancy during injury or surgery
- Osteoporosis that influence rehabilitation or surgery

Intraoperatively:
- No complete tear at arthroscopy (partial tear or intact ACL) or only partially a proximal tear

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	74
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	25-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52403
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9072
CCMO	NL67842.018.20
OMON	NL-OMON52403

Resultaten

Samenvatting resultaten
None yet; will be updated accordingly