# Acute anterior cruciate ligament rupture: RecOnsTruction Or Repair?

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Primary goal: Investigate the hypothesis that suture repair of a ruptured vkb, combined with a dynamic intraligamentary stabilization and microfracture of the femoral notch, results in at least equal effectiveness compared with an ACL reconstruction...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45094

**Source**
ToetsingOnline

**Brief title**
ROTOR study

### Condition

- Other condition
- Tendon, ligament and cartilage disorders

**Synonym**
anterior cruciate ligament rupture

**Health condition**

voorste kruisband chirurgie

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Ziekenhuisgroep Twente
**Source(s) of monetary or material Support:** OCON

## Intervention

**Keyword:** Acute Anterior Cruciate Ligament (ACL), Dynamic Intraligament Stabilisation (DIS), Reconstruction, Suture repair

## Outcome measures

### Primary outcome

Self-reported functional outcome at one-year follow post surgery measured by the IKDC 2000 subjective scale.

### Secondary outcome

Secondaire eindpunten: Self-reported functional outcome at one-year follow post surgery measured by the IKDC 2000 subjective scale 6 weeks, 3,6 and 9 months, 2,5 and 10 years post surgery, self-reported disabilities (KOOS), level of physical activity (Tegner), satisfaction (VAS) as well as IKDC physical examination (clinimetretrics) 6 weeks, 3, 6 en 9 months, 1, 2, 5 and 10 years post surgery; instrumented anteroposterior laxity, leg symmetry index for jump tests as well as isokinetic quadriceps en hamstrings force 6 en 9 months, 1, 2, 5 en 10 years after surgery; biomechanical parameters jump tests with 3D motion sensors (hip flexion-, knee flexion- and knee varus angles at initial landing contact) 1 and 2 years after surgery and a sport-specific fatigue test with electromyography (EMG) and 3D motion sensors (a repeated measures ANOVA with Bonferroni post-hoc analysis of the quadriceps/hamstring activation ratio, hip flexion-, knee flexion- and knee varus angles) between 10-18 months after surgery; radiologic signs of arthrosis 1,2 5 and 10 years post surgery;

reruptures of the ACL within 10 years post surgery, classification rupture

pattern peroperative.

# Study description

### Background summary

An anterior cruciate ligament rupture is a serious injury to the knee with high probability of the occurrence of dynamic instability, accompanying lesions and early post-traumatic arthrosis. Despite conservative treatment through rehabilitation or ACL reconstruction surgery not all patients do return to their previous activity levels. Moreover degenerative changes, especially early posttraumatic arthrosis, are not counteracted.
In order to optimize the clinical results after ACL surgery, a renewed interest has emerged in healing the patient's own ruptured ACL after attaching. Literature suggests that with the current innovations in surgical repair techniques of (natural) healing of a ruptured ACL may result in similar clinical outcomes in comparison to the gold standard, the ACL reconstruction. In addition, it may even reduce degenerative changes occur in relation to the gold standard. Moreover, the return to daily activities and sports level seems significantly faster than after ACL reconstruction.
The hypothesis is that a suture (suture repair) of a ruptured ACL, combined with a dynamic intraligamentary stabilization, as well as microfracture of the femoral notch, passes, at least equal efficacy in comparison with an anterior cruciate ligament reconstruction using autologous hamstrings in terms of functional recovery 1 years postoperatively.
The DIS bonding technique will be applied in the current study to surgically repair (suture) the ruptured ACL. DIS is an abbreviation and stands for intraligamentary dynamic stabilization (DIS). DIS has been used in humans and seems to provide a high patient satisfaction, favorable clinical and radiological results. However, to our knowledge, to date, no randomized comparative study has been conducted yet in which the DIS technique is compared with the gold standard, the ACL reconstruction.

### Study objective

Primary goal:
Investigate the hypothesis that suture repair of a ruptured vkb, combined with a dynamic intraligamentary stabilization and microfracture of the femoral notch, results in at least equal effectiveness compared with an ACL reconstruction using autologous hamstring in terms of functional recovery one year postoperatively in terms of a patient self-reported outcome related to be able to conduct daily and sporting activities.

Secondary objective:
Evaluation of clinical outcomes - including isokinetic force- and jump tests, instrumented jump tests 1 and 2 years post-operative and an instrumented sport-specific fatigue test including jump tests (in a subgroup (n=6-8) between 10-18 months after repair surgery) -, self-reported by the patient outcomes, osteoarthritis, rehabilitation time required for return to daily and sporting activities and levels of sporting activity which has returned in patients with status after an ACL rupture and suture repair augmented with a dynamic intraligamentary microfracture and stabilization of the femoral notch in comparison with an anterior cruciate ligament reconstruction with the ipsilateral hamstring graft.

**Study design**

This study is a single center stratified block randomized controlled trial. Patients with ACL rupture, confirmed by an orthopedic surgeon based on the outpatient history and radiographic images, will be randomized into an experimental ('repair' / DIS) group after inclusion and a control (reconstruction, regular care) group. Patients will be stratified on the level of sport/physical active practice, on the basis of the Tegner score. The Tegner score is an evaluative and inventory questionnaire on which the patient indicates the gravity of his work and/or sports activities. A higher score is associated with a higher level of physical strain/activity . On the basis of the Tegner score patients will be stratified into a 'moderate' physically active stratum (group Tegner score 5-6-7) and 'highly' physically active stratum (group Tegner score 8 -9-10). Stratification based on the degree of physical activity is considered to be important because the extent and severity of physical activity/strain in daily life poses a potential (difference) in risk of re-rupture between the two study arms. In order to minimize potential differences in 'exposure' or 'risk of re-rupture' between the two study groups stratification is relevant.Measurements take place at baseline, peri-operative / immediately after surgery, 6 weeks, 3,6,9 months and 1, 2, 5 and 10 years postoperatively. The instrumented jump tests take place at 1 en 2 years follow-up. The sport-specific fatigue test (in which the patient has to run and pivoting for 4x15 minutes about a distance of 20 meters started with, every 15 minutes alternating with, and ending with jump tests (drop vertical jump, single leg hop and hold, triple hop for distance, both legs)) will take place within 6 months after 1 year follow-up.

**Intervention**

n=48 patients will participate in the current study. n=33 at OCON and n=15 at HAGA. Patients will be assigned to a suture repair of the ruptured vkb complemented by a dynamic intraligamentary stabilization (DIS) and microfracture of the femoral notch or the gold standard, a ACL reconstruction.

**Study burden and risks**

Patients are asked preoperative, perioperative / immediate postoperative, 6 weeks postoperatively, 3,6,9 and 12 months postoperatively, 2.5 and 10 years postoperatively to fill out a questionnaire booklet and undergo clinimetric testing by a sports physiotherapist. Compared with usual care, only the time points 5 and 10 years postoperatively are an additional burden for patients.

- 5x questionnaires subjective IKDC, KOOS, Tegner and VAS (estimated completion time 10 minutes). The questionnaires will be taken digitally. In addition, the WAI shortened measurement will be filled in any time point, we do not use it in the regular care.
- 5x clinimetrics: IKDC physical examination, instrumented AP laxity, LSI jump-force testing, instrumented jump tests and sport-specific fatigue test. The clinimetric tests (except the sport-specific fatigue test) will be executed by an experienced and specialized ACL sports physiotherapist. The total time for instruction, conducting, and documenting these tests will vary from person to person but is estimated at a maximum of 35 minutes. The instrumented jump tests requires an estimated additional duration of 10 minutes to attach the sensors. The sport-specific fatigue test will take a maximum of 2 hours per person. There is no risk during the fatigue test, as the measurements consist of movements during normal sport activities.
- Compared to regular care two additional x-ray pictures will be taken in the context of the study (on 5 and 10 years postoperatively). A subset of 6-8 patients between 10-18 months after repair surgery will undergo a sport-specific fatigue test.

Preparation, duration of surgery (both at 45 minutes) and directive to dismiss will be equal for both groups. In addition, patients who decide to participate in the current study must be willing to comply with a post-operative rehabilitation trajectory at a sports physiotherapist (average of 2 times per week).

Patients in the repair group can be upon request of the patient (in the absence of an medical indication) re-operated during day surgery (spinal aneasthesia) to remove the fixation screw of the DIS ligament. After surgery, patients are recommend a full weight bearing protocol postoperatively (guided by the pain). The removal will occur after the 12 months control moment of the study.

# 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

- Sportive, active patient (Tegner score =/>5)
- Age above 18 untill 30 years at time of inclusion
- Primary rupture of the anterior cruciate ligament, evidence by history (acute trauma, clicking sensation, swelling within a few hours, instability) and physical examination (positive Lachman, anterior drawer test and/or Pivot shift)
- Primary rupture indicated by MRI
- No associated ligamentuous disorde of the knee, evidenced by history, physical examination, x-ray or MRI)
- Time span between anterior cruciate ligament rupture and operation no longer than 21 days
- Willingness to comply to advised rehabilitation protocol supervised by NFVS registrated sports physiotherapist

## Exclusion criteria

- Infection
- Known hypersensitive response for materials used (Cobalt, chroom, nickel)
- Serieus pre-existing malaligment of leg indicated for surgery

- Tendency for excessive scar tisseu formation, such as arthrofibrosis
- History of previous surgery on leg indicated for surgery
- History of removal of tendon on leg indicated for surgery
- Muscular, neurological or vascular disorders negatively affecting healing or rehabilitation
- Cartilage injury requiring (some kind of) cartilage repair surgery (such as microfracture or cell therapy)
- Arthrosis more dan ICRS grade 2 evidenced by x-ray
- Long(er) term use of relevant medication, such as prednisolon or cytostatica
- Pregnancy
- Know osteoporosis

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Other |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 30-10-2014 |
| Enrollment: | 48 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 30-09-2014 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

Approved WMO

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| Date: | 17-08-2015 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 08-11-2016 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 21-04-2017 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 |
|---|---|
| Other | na goedkeuring clinical trials gov |
| CCMO | NL50116.044.14 |

# Study results

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| Results posted: | 22-06-2020 |
| Actual enrolment: | 48 |

**First publication**
22-06-2020