

STUDY PROTOCOL

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Repair versus reconstruction for proximal anterior cruciate ligament tears: a study protocol for a prospective multicenter randomized controlled trial

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Abstract

Background: For active patients with a tear of the anterior cruciate ligament (ACL) who would like to return to active level of sports, the current surgical gold standard is reconstruction of the ACL. Recently, there has been renewed interest in repairing the ACL in selected patients with a proximally torn ligament. Repair of the ligament has (potential) advantages over reconstruction of the ligament such as decreased surgical morbidity, faster return of range of motion, and potentially decreased awareness of the knee. Studies comparing both treatments in a prospective randomized method are currently lacking.

Methods: This study is a multicenter prospective block randomized controlled trial. A total of 74 patients with acute proximal isolated ACL tears will be assigned in a 1:1 allocation ratio to either (I) ACL repair using cortical button fixation and additional suture augmentation or (II) ACL reconstruction using an all-inside autologous hamstring graft technique. The primary objective is to assess if ACL repair is non-inferior to ACL reconstruction regarding the subjective International Knee Documentation Committee (IKDC) score at two-years postoperatively. The secondary objectives are to assess if ACL repair is non-inferior with regards to (I) other patient-reported outcomes measures (i.e. Knee Injury and Osteoarthritis Outcome Score, Lysholm score, Forgotten Joint Score, patient satisfaction and pain), (II) objective outcome measures (i.e. failure of repair or graft defined as rerupture or symptomatic instability, reoperation, contralateral injury, and stability using the objective IKDC score and Rollimeter/KT-2000), (III) return to sports assessed by Tegner activity score and the ACL-Return to Sports Index at two-year follow-up, and (IV) long-term osteoarthritis at 10-year follow-up.

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Discussion: Over the last decade there has been a resurgence of interest in repair of proximally torn ACLs. Several cohort studies have shown encouraging short-term and mid-term results using these techniques, but prospective randomized studies are lacking. Therefore, this randomized controlled trial has been designed to assess whether ACL repair is at least equivalent to the current gold standard of ACL reconstruction in both subjective and objective outcome scores.

Trial registration: Registered at Netherlands Trial Register ([NL9072](#)) on 25th of November 2020.

Keywords: Anterior cruciate ligament, Anterior cruciate ligament reconstruction, Anterior cruciate ligament repair, Primary repair, Proximal tear, Knee injury, Suture repair, Remnant, Ligament preservation

Background

Historical overview of ACL repair

The first documented surgical treatment of an anterior cruciate ligament (ACL) injury consisted of open repair in 1895 when Mayo Robson repaired a proximally avulsed ACL and posterior cruciate ligament back to the femur in a 41-year old male with good outcomes at six-year follow-up [1]. In the twentieth century, Ivar Palmar [2, 3] and Don O'Donoghue [4, 5] reported on open primary repair as a treatment of ACL injuries, and in the early 1970s open primary repair became a popular treatment for ACL injuries [6–9].

Feagin and Curl were the first to present the outcomes of open repair in 1972 and noted good outcomes at short-term follow-up [8]. A few years later in 1976, however, they noted a deterioration of outcomes at mid-term follow-up in their cohort [10]. Similarly, several other surgeons and researchers noted good short-term [11–16] but disappointing mid-term outcomes [17–21]. With these disappointing results and the promising outcomes of ACL reconstruction, several (randomized) prospective studies were started in the 1980s comparing open ACL repair with open ACL reconstruction [19, 22–24]. These prospective studies noted more reliable outcomes with ACL reconstruction when compared to ACL repair, which ultimately led to an abandonment of open ACL repair and to the current gold standard of ACL reconstruction for all patients [9].

In 1991, Sherman et al. were the first analyzing the disappointing mid-term outcomes of open ACL repair by performing an extensive subgroup analysis [21]. The authors found that a trend towards better outcomes in patients with proximal avulsion type tears and good tissue quality when compared to patients with midsubstance tears and/or tears with poor tissue quality. Unfortunately, the inclusion of the aforementioned prospective trials was already completed before the study by Sherman et al. was published, and thus the prospective trials contained all tear types including patients that might not have been ideal candidates for ACL repair (i.e., those with midsubstance tears or tears with poor tissue quality).

When critically reviewing the historical literature, and bearing in mind these findings by Sherman et al., it can be noted that the results of open repair of proximal ACL tears were indeed better. A recent systematic review of all historical studies on open repair noted that outcomes of open repair of proximal ACL tears showed 83 to 90% clinical stability, 80% return to sports, 79% good to excellent Lysholm score and 86% satisfaction in 539 patients in 11 studies [25]. These findings indicate that ACL repair may have been prematurely abandoned for all tear types and perhaps may be a good treatment option for patients with proximal tears. Furthermore, outcomes of ACL repair can be expected to improve when benefiting from modern development, such as arthroscopy (instead of open repair) and modern rehabilitation (instead of casting and immobilization).

Rationale for ACL repair

The rationale behind better outcomes of ACL repair of proximal tears compared to midsubstance tears is that better vascularity is present at the proximal end of the ligament [26] and, as a result, proximal tears have healing potential for reattachment that is similar to medial collateral ligament (MCL) tears [27]. The reason for the continued pursuit of repair as a treatment of ACL injuries can also be explained by the potential advantages of repair over reconstruction. With ACL repair, the native tissue can be preserved along with proprioception which may provide patients with a more normal feeling of the knee compared to ACL reconstruction [28, 29]. Also, ACL repair is a less invasive surgery when compared to ACL reconstruction as no (or only small) tunnels need to be drilled and no graft tissues need to be harvested, leading to lower surgical morbidity [30–33], faster return of range of motion and fewer complications [34]. Furthermore, in case of failure of both treatments, revision surgery following primary repair is expected to be similar to primary reconstruction (no or only small tunnels have been drilled or grafts harvested), whereas revision of reconstruction surgery can be complicated by tunnel malpositioning or widening and pre-existing hardware

and is associated with inferior outcomes compared to primary ACL reconstruction [35–37].

Recent literature on ACL repair

With the recognized relevance of tear location in ACL repair and the potential advantages of this treatment, several surgeons and researchers have pursued the concept of ACL repair of proximal tears [38–47]. Most of these studies were retrospective small case series reporting good short-term outcomes with an overall reported failure rates of 6 to 9%, reoperation rates of 0 to 4% and patient-reported outcome measures (PROMs) > 85% of the maximum score [48]. Three studies have also shown that the good outcomes are maintained at mid-term follow-up [44, 45, 49]. One prospective study has compared the outcomes of repair ($n = 20$) versus reconstruction ($n = 20$) in patients with proximal tears and reported similar outcomes regarding functional outcomes, failure rates and laxity examination [46]. However, no randomized studies or studies with sufficient number of patients to assess differences between the treatments have been performed, and a recent systematic review also concluded higher-level evidence studies for ACL repair are currently lacking [48]. Recent studies have also suggested that primary repair with suture augmentation results in lower failure rates when compared to primary repair without suture augmentation [42, 48].

The current surgical gold standard of treating ACL injuries is ACL reconstruction using autograft tissue of either hamstring tendons, patellar tendon or quadriceps tendon. As for all new surgical techniques, the outcomes of arthroscopic ACL repair need to be compared to the current gold standard in order to assess whether this treatment can be used for standard patient care. Therefore, a randomized controlled trial (RCT) comparing ACL repair with ACL reconstruction is needed. The ACL study group of the Dutch Arthroscopy Association also recently declared that “*the application of ACL repair could be considered in a medial ethical committee-approved study until there is high-grade and long-term evidence regarding the efficacy of modern-day ACL repair.*”

Goal and hypotheses

The goal of this multicenter non-inferior prospective randomized controlled trial is therefore to compare the outcomes of arthroscopic ACL repair with suture augmentation to ACL reconstruction for patients with proximal tears in a 1:1 allocation ratio. The primary outcome is the subjective International Knee Documentation Committee (IKDC) score and the secondary outcomes are other patient-reported outcomes, objective outcomes and return to sports. It is hypothesized that patients following ACL repair with suture augmentation have non-

inferior primary and secondary outcomes when compared to ACL reconstruction due to the less invasive surgery.

Methods

This study and manuscript have been designed in accordance to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.

Study design

This study is a multicenter prospective RCT with randomization into two treatment arms: (I) arthroscopic ACL repair with suture augmentation and (II) arthroscopic ACL reconstruction surgery. This study is a non-inferiority study with the hypothesis that arthroscopic ACL repair is non-inferior to (equivalent or better than) arthroscopic ACL reconstruction. All patients with proximal tears will be randomized during the operation into one of these treatment arms and will be followed up to 10-years postoperatively.

Study sample

Potential candidates will be selected from five participating orthopaedic surgery departments, of which one is an academic hospital, three are teaching hospitals and one is a private hospital. Inclusion and exclusion criteria for participation in the study are displayed in Table 1. In general, potential inclusion involves all patients with acute, isolated, complete, proximal ACL tears that have a desire to return to pre-injury activities and exclusion involves all concomitant ligamentous and osteoarthritic injuries and skeletally immature patients. A flowchart of the study is shown in Fig. 1. Patients can withdraw their participation in this study at any time point, at which their data will be deleted.

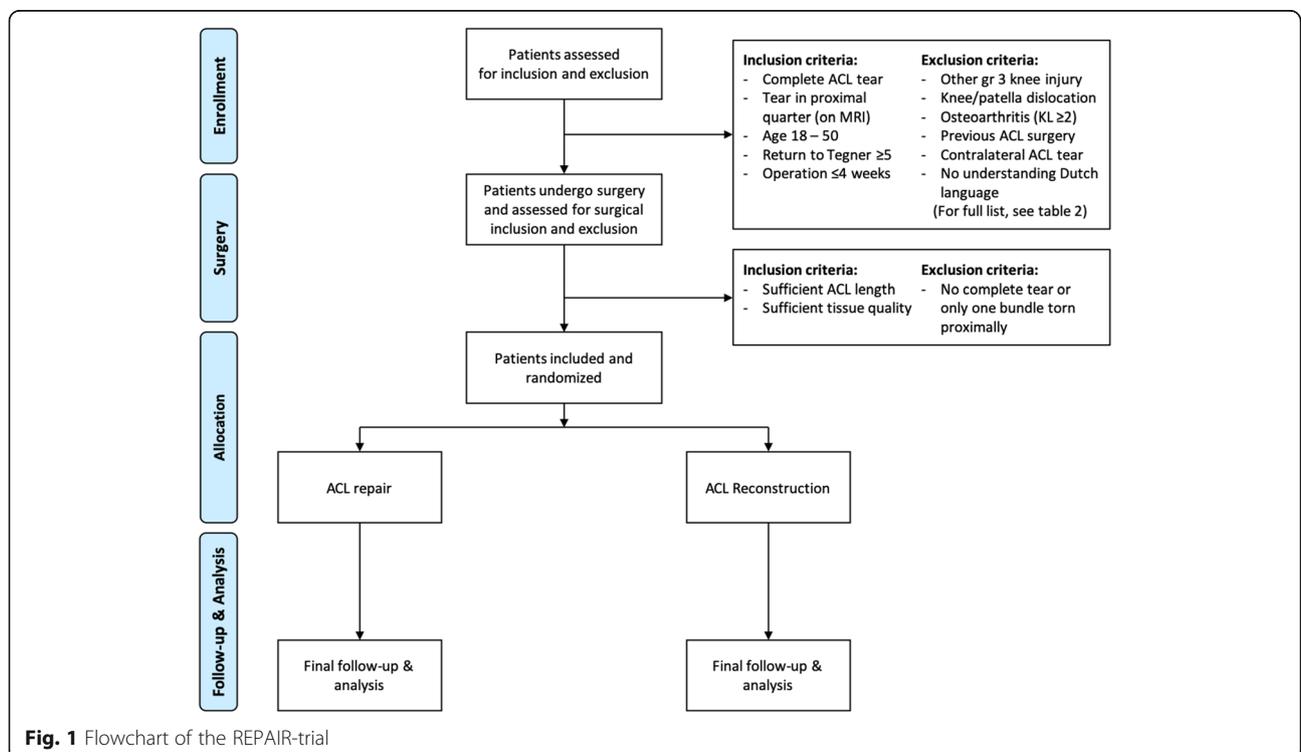
Randomization

All patients will be consented preoperatively for the study. Patients are taken into the operating room, general or epidural anesthesia is induced, and the leg is prepped and draped for standard arthroscopic knee surgery with a tourniquet high at the upper thigh. Then standard anteromedial and anterolateral portals are created, and the knee is assessed for cartilage, meniscus and ligamentous injuries. After cartilage and meniscus injuries are addressed, the tear type of the ACL and eligibility for this study is assessed. First, it should be confirmed whether a proximal tear is present (i.e., whether the distal remnant of the ACL is of sufficient length to be reattached to the anatomical femoral footprint of the ACL) and whether sufficient tissue quality is present (i.e., whether the ligament remnant is of sufficient quality to withhold suture passage and can be tensioned towards the femur).

Table 1 Inclusion and exclusion criteria for participating in this trial

Inclusion criteria	Exclusion criteria
Pre-operative	
Complete primary ACL tear on physical examination and MRI	Complete ipsilateral concomitant knee ligament injury requiring surgery
Tear in proximal quarter on MRI [50, 51]	Concomitant ipsilateral knee dislocation or patellar dislocation
Age 18 – 50 years [22, 52]	Osteoarthritis KL grade ≥ 2
Preinjury Tegner level ≥ 5 & desired Tegner level ≥ 5 [53]	Previous ipsilateral ACL reconstruction/repair
Operation within 4 weeks of injury [54]	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 procedures
	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
Intra-operative	
Sufficient tissue length for retensioning to femoral insertion	No complete tear at arthroscopy or only one bundle (AM or PL) with proximal tear
Sufficient tissue quality to withhold sutures	Grade 3 or grade 4 cartilage lesions

ACL indicates anterior cruciate ligament; MCL, medial collateral ligament; LCL, lateral collateral ligament; PCL, posterior cruciate ligament; PLC, posterolateral corner.



reasons. However, the data analysis will be performed in blinded fashion.

Primary outcomes/endpoint (Table 2)

The primary outcome of this non-inferiority RCT is the subjective patient reported outcome (PROM) at two-year follow-up consisting of the subjective IKDC score [63] (Dutch validation [64]), as to a recent RCT on a similar topic [65, 66]. The primary endpoint is the subjective IKDC at two-years postoperatively. Patients will ultimately be followed for 10 years.

Secondary outcomes (Table 2)

The secondary outcomes of this RCT are fourfold and consist of (I) other subjective outcomes, (II) objective outcomes, (III) return to sports, and (IV) long-term osteoarthritis.

Other collected PROMs for this study are the Knee Injury and Osteoarthritis Outcome Score (KOOS) [67] (Dutch validation [68]), Lysholm score [69] (Dutch validation [70]), and Forgotten Joint Score (FJS) [28] (Dutch validation [71]). Furthermore, patient satisfaction and pain scores are collected using a numeric rating scale (range 0 – 10).

The objective outcomes consist of failure of ACL repair/graft, reoperation, contralateral injury, and laxity. Failure is defined as a (traumatic) rerupture or symptomatic instability with activities. Reoperation is defined as any new operation on the same knee for any other

reason than revision (e.g., symptomatic meniscus tear, hardware irritation, infection or stiffness/arthrofibrosis). Contralateral injury was defined as a complete ACL rupture of the contralateral ACL. Stability is defined as the laxity found with physical examination using the IKDC objective score form [72], which includes the Lachman, anterior drawer and pivot shift test, and side-to-side differences is assessed using KT-2000 or Rollimeter.

Return to sports is defined as (I) returning to sports, (II) returning to the same sport, and (III) returning to the preinjury level of sport. The preinjury and postoperative Tegner activity scale are also collected, which enables comparison with other studies [73] (Dutch validation [70]). Finally, confidence of return to sports and fear of reinjury are assessed using the ACL-Return to Sports Index (ACL-RSI) score [74] (Dutch validation [75]).

Osteoarthritis will be reviewed at 10-year follow-up. Radiographs of both knees will be performed, and the operated knee will be compared to (I) the contralateral knee if no operation occurred in that knee, and (II) the ipsilateral knee radiograph preoperatively. The Kellgren-Lawrence (KL) grade will be used to assess the incidence and grades of osteoarthritis.

Sample size

The sample size calculation was based on the primary outcome of this study (subjective IKDC score), similar to another RCT design on this topic [65]. It has been

Table 2 This chart provides an overview of which outcomes are collected at the different follow-up visits

	Pre	3 mns	6 mns	9 mns	1 yr	2 yrs	5 yrs	10 yrs
Primary outcomes								
IKDC subjective	X	X	X	X	X	X	X	X
Secondary outcomes								
KOOS	X	X	X	X	X	X	X	X
Lysholm	X	X	X	X	X	X	X	X
Forgotten Joint Score	X	X	X	X	X	X	X	X
Satisfaction & pain	X	X	X	X	X	X	X	X
Failure		X	X	X	X	X	X	X
Reoperation		X	X	X	X	X	X	X
Contralateral injury	X	X	X	X	X	X	X	X
IKDC objective	X	X	X	X	X	X	X	X
KT-1000	X	X	X	X	X	X	X	X
Return to sports		X	X	X	X	X	X	X
Tegner score	X	X	X	X	X	X	X	X
ACL-RSI		X	X	X	X	X	X	X
Osteoarthritis (X-ray)	X							X
AE, SAE, SUSAR	X	X	X	X	X	X	X	X

IKDC indicates International Knee Documentation Committee, KOOS Knee Injury and Osteoarthritis Outcome Score, AE adverse events, SAE serious adverse event, SUSAR Suspected Unexpected Serious Adverse Reaction, Pre preoperatively, mns months, yr(s) year(s)

shown that a difference of 8.8 points in the subjective IKDC score is the minimal clinically important difference (MCID) [76]. Using this non-inferiority limit of 8.8 points, and a standard deviation of 11 points [42, 65, 77] along with a two-sided alpha of 0.05, a power of 90%, and a lost-to-follow-up rate of 10%, a total of 37 patients in each group (74 patients in total) are needed to assess the primary outcome of this non-inferiority RCT. This sample size is also sufficient for the MCID of KOOS [78] and Lysholm score [79]. Given the recent studies that showed that 30-40% of the acute tears will have repairable proximal ACL tears [50, 80], we estimate that approximately 200 patients will be needed to be screened preoperatively to achieve the sample size of 74 patients [81].

Statistical analysis

Both an intention to treat analysis and per protocol analysis will be performed for this non-inferiority study. Comparison of nominal variables between ACL repair and ACL reconstruction will be performed using two-by-two tables with Pearson's Chi-square test or Fisher's exact test (in case one of the cells is < 5). For comparison of continuous variables, first tests for normal distribution of values are performed and independent t-tests are used of normal distributed values and non-parametric t-tests are used for not-normally distributed values.

A mixed model analysis for repeated measures will be performed to assess differences between both groups. Furthermore, a multivariate regression analysis will be performed for the primary endpoint of IKDC at two-years follow-up in order to correct for potential confounders. Statistical analysis will be performed using SPSS version 25.0 (IBM Software, Armonk, NY, USA). All tests are two-sided and a *p*-value of < 0.05 is considered statistically significant.

Discussion

This study reports on the study design of the REPAIR-trial (Repair versus rEConstruction for Proximal Anterior cruciate Ligament tearS). Few studies have examined the outcomes of repair versus reconstruction with favorable outcomes for ACL reconstruction [22–24]. However, these studies were performed over 30 years ago and are limited by the fact that all tear types were repaired rather than only proximal tears and that repair was performed using an arthrotomy [9, 25, 82]. Recently, four RCT studies have been designed to assess the outcomes of ACL repair [65, 83–85] but these are either performed in midsubstance tears [65, 83], assess the outcomes of dynamic intraligamentary stabilization (DIS) versus ACL reconstruction [65, 83], repair versus DIS [84] or Bridge-Enhanced ACL Repair (BEAR) with

reconstruction [85]. Our current RCT differs from these studies as only proximal tears will be treated rather than all tear types and as the ligament will be reattached to the femoral footprint in a minimally invasive way.

The renewed interest of repair of proximal tears can be explained by improved understanding of patient selection. Research has shown that proximal tears have a better vascularity compared to midsubstance tears [26] and therefore have excellent healing capacity by reattachment to the femoral wall which is similar to the healing capacity of MCL tears [27]. Both historical studies on open ACL repair [9, 25, 82] and more recent studies on repair with DIS (also known as Ligamys) have shown that the clinical outcomes are indeed better when repairing proximal tears. Two studies have shown failure rates of repair with DIS in midsubstance tears of 24% in all patients and 36% in competitive athletes with midsubstance tears [86, 87]. Our current study applies strict patient selection criteria of proximal tears and good tissue quality. As the length of distal remnant and possibility of repair can only be assessed intraoperatively, randomization in this study should perform during surgery after the surgeon has confirmed the possibility of repair. Consequently, patients will be consented that they might be excluded during surgery if a non-repairable tear is present, and these patients will undergo standard ACL reconstruction.

It should be noted that there is also a potential disadvantage of ACL repair. By performing ACL surgery in the early phase (since early surgery prevents ligament retraction and preserves tissue quality that is both needed for repair [4, 5, 88]), it is likely that too many ACL surgeries will be performed. Current day standards recommend that patients following ACL injury will be treated conservatively first as approximately half of the patient may be copers and do not need surgical intervention [53, 60, 89]. By performing surgery on all ACL injured patients, patients will undergo surgery while they might be copers and do not need surgery. This risk is minimized in this study by only including patients aged 18 – 50 and only patients that desire to return to sports. It would be best if it is known preoperatively which patients will not do well with conservative treatment and ultimately require ACL surgery, as this both increases the chance of performing ACL repair and as early reconstruction outcomes decreases the risk for meniscal and chondral damage [60] at longer follow-up when compared to delayed reconstruction.

Several studies have recently reported good short-term outcomes of arthroscopic ACL repair using different techniques: in some studies femoral fixation consisted of using two suture anchors [42, 44], one suture anchor (for both bundles) [40, 45, 46] or transosseous tunnels with or without cortical button fixation [39, 41, 43, 55,

90], and some studies used ACL repair without [40, 41, 45, 46] or with [39, 43, 55, 90] additional suture augmentation. For this study, femoral fixation will consist of cortical button fixation with additional suture augmentation (FiberTape) in order to protect the repair in the early phases of rehabilitation, because it has been suggested that additional suture augmentation leads to lower rerupture rates [42, 48].

This study has been designed to assess the outcomes following repair and reconstruction of proximal ACL tears. We hypothesize that the repair treatment is a good treatment for proximal tears as it has potential advantages over ACL reconstruction: the surgery is short and minimally invasive, it has a low complication rate, rehabilitation is easier, and in case ACL repair fails then primary reconstruction surgery can be performed. Non-inferiority of arthroscopic ACL repair compared to arthroscopic ACL reconstruction may lead to a treatment algorithm in which patients with proximal avulsion tears can be repaired in the acute setting whereas patients with midsubstance tears will undergo ACL reconstruction in either the acute or delayed setting [91, 92].

Abbreviations

ACL: Anterior Cruciate Ligament; ACL-RSI: Anterior Cruciate Ligament - Return to Sports Index; BEAR: Bridge-Enhanced ACL Repair; DIS: Dynamic Intraligamentary Stabilization; FJS: Forgotten Joint Score; IKDC: International Knee Documentation Committee; KOOS: Knee Injury and Osteoarthritis Outcome Score; MCID: Minimal Clinically Important Difference; MCL: Medial Collateral Ligament; PROM: Patient-Reported Outcome Measure; RCT: Randomized Controlled Trial; REPAIR-trial: Repair versus rEconstruction for Proximal Anterior cruciate ligament tears trial; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

Acknowledgments

Not applicable.

Authors' contributions

JPvdL conceived of the study. AvN, GMMJK, MVR and JPvdL initiated the study design. INS provided statistical expertise in clinical trial design and INS and HDV are conducting the primary statistical analysis. MVR, RvD, MLMF, GTTH, RAGH, WAvdW, AvN and GMMJK will be performing the operations. All authors contributed to refinement of the study protocol and approved the final manuscript.

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Availability of data and materials

Available at study publication.

Declarations

Ethics approval and consent to participate

This study has been approved by the Medical Ethics Committee of the Amsterdam Medical Center on the 16th of February 2021 under the reference numbers 2020_322#B202163 and 2020_322#B202189 and approval is for all sites. The study has been registered at the Netherlands Trial Register (NL9072) on 25th of November 2020. All patients will be asked to give their written informed consent for this study and can stop participation of this

study at any time point, at which their data will be deleted. The results of this study will be presented at national and international conferences and peer-reviewed journals in a de-identified manner.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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