Graft selection in anatomic anterior cruciate ligament reconstruction Patella, hamstrings or quadriceps tendon autograft

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Primary objective:To investigate the hypothesis that an anatomic single bundle anterior cruciate ligament reconstruction with a (flat) quadriceps tendon autograft is at least as effective as reconstruction of the ruptured anterior cruciate ligament...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON46939

Source
ToetsingOnline

Brief title
Graft type

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym
Anterior cruciate ligament rupture

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: OCON;Martini Ziekenhuis en Ziekenhuis Gelderse Vallei eigen financiering

Intervention

Keyword: Anterior cruciate ligament rupture, Autograft, Failure, Graft type

Outcome measures

Primary outcome

Failure= presence of pathological laxity, complaints of knee instability in the absence of any pathological laxity and/or discontinuïty of the graft on MRI or arthroscopy.

Secondary outcome

Secondary outcome measures and study parameters are displayed below. Follow-up measurements are perfomed at 6 weeks, 6 months, 1, 2, 5 and 10 years postoperatively.

Secondary outcomes

• ACL-QOL

• Failure

• IKDC 2000 subjective knee evaluation score

PROM's

• KOOS (Knee injury and Osteoarthritis Outcome Score), demographic form, current health assessment form, knee history form

• Tegner Score

• Lysholm Score

• VAS Anterior Knee Pain score during rest

• VAS Anterior Knee Pain score during activity

• VAS Kneeling Pain score

• VAS Contentment score

Clinimetrics

• IKDC 2000 physical examination score

• Instrumented anteroposterior laxity (Rolimeter)

• Leg Symmetry Index (LSI) jump tests

Radiology

• Kellgren-Lawrence (KL) score

Other

• Monitoring and registration of standard side effects, complications and/or new knee injuries (contact or non-contact) that occur during the whole study, when relevant in relation to specific details from the surgery reports.

optionally:

Patiënts from OCON will be asked to wear movement sensors during the execution of the regular hop tests (6 months, 1 jaar en 2 jaar) in order to be able to more objectively examine knee (flexion/extension, valgus/varus), ankle en hip

angles.

Study description

Background summary

Background

A rupture of the anterior cruciate ligament (ACL) is a severe injury of the knee. The current gold standard treatment for young and active patients with instability, is a surgical ACL reconstruction. However, anno 2014 there is no consensus on which graft is best suited for this.
Paradigms on the different types of auto grafts and their weaknesses and benefits originate mostly from the eighties and nineties, when the patella tendon was being replaced by the hamstring graft as the *new* gold standard. Nowadays, the philosophy of isometric tunnel placement has been abandoned, and has been replaced by the philosophy of anatomic reconstructions. The question then arises: Are the results of the comparative studies, and the current paradigms, still applicable, now that the philosophy has transitioned from isometric to anatomic tunnel placement?

The hamstring autograft is currently the most used graft for ACL reconstruction worldwide, despite the disadvantages compared to the patellatendon autograft, such as a higher re-rupture and revision percentage when used in patients under 25 years old. The question then arises: Is it justified that the hamstringgraft is the most used graft worldwide?
Rehabilitation protocols are often not, or poorly, described, despite it*s significant effect on the outcome and co morbidity of an ACL reconstruction. Especially anterior knee pain, which is often mentioned as a disadvantage of the patellagraft, is significantly influenced by rehabilitation protocols. The introduction and implementation of a nation-wide evidence-based rehabilitation protocol in The Netherlands created uniformity of treatment, and the possibility to generalise scientific conclusions. The question then arises: Due to new insights in rehabilitation and implementation of new protocols, is the anterior knee pain, the often mentioned disadvantage of the patella tendon graft, still a relevant disadvantage?

The quadriceps tendon autograft is a less often used graft. Nevertheless, research has shown that it seems like a good alternative for the patellatendon and hamstring autograft. Functional outcome is similar, while less donorsite morbidity is reported compared to the patellatendom and hamstring autograft.. The question then arises: Is it fair that the quadriceps tendon is rarely used as an autograft for ACL reconstruction?

Increasing knowledge of the anatomy of the ACL results in new insights in the methods to achieve true anatomic ACL reconstruction. New arguments support the use of the patella tendon - and even the quadriceps tendon - over the use of the hamstringgraft, because their anatomic similarities to the anterior cruciate ligament might be better suited to restore knee kinematics. The question then arises: Are the flat-shaped patella tendon autograft and quadriceps tendon autograft better suited to restore the anatomy of the ruptured ACL than the round hamstring graft?

Hypothesis
The hypothesis is that anatomic reconstruction of the ruptured anterior cruciate ligament with a (flat) quadriceps tendon autograft is at least as effective as reconstruction of the ruptured anterior cruciate ligament with a patellatendon autograft or a hamstringtendon autograft, in terms of failure, measured 2 years postoperatively. Failure is defined as pathological laxity, complaints of knee instability in the absence of any pathological laxity and/or discontinuïty of the graft on MRI or arthroscopy.

Study objective

Primary objective:
To investigate the hypothesis that an anatomic single bundle anterior cruciate ligament reconstruction with a (flat) quadriceps tendon autograft is at least as effective as reconstruction of the ruptured anterior cruciate ligament with a patellatendon autograft or a hamstringtendon autograft, in terms of failure, measured 2 years postoperatively. Failure is defined gedefinieerd as pathological laxity, complaints of knee instability in the absence of any pathological laxity and/or discontinuïty of the graft on MRI or arthroscopy.

Secondary objectives:
patient reported outcome measures (PROMs), clinimetrics, radiological assessment, duration of rehabilitation necessary for return to sports and daily activities and the level of sport activities to which the patient returned, in patients treated with an anterior cruciate ligament reconstruction using a patellatendon autograft, hamstringtendon autograft of quadricepstendon autograft, as measured in the short-term (6 weeks, 6 and12 months postoperatively), mid-term (2 years postoperatively), and long-term (5 and 10 years postoperatively).

Study design

Multicenter blocked stratified randomised controlled trial with varying block sizes (n=2, 4, 6, 8). Patients with an anterior cruciate ligament rupture, confirmed by an orthopaedic surgeon (as evident from anamnesis, physical examination and radiographic imaging) who fit the inclusion criteria and do not have any of the exclusion criteria, will be asked to participate in this study.

Baseline measurements will be performed, after informed consent is obtained. Allocation of treatment of the included patients will be performed in the operating room (OR), where patients will be randomised (blocked and stratified) per clinic, to have ACL reconstruction with a patellatendon autograft, hamstring tendon autograft or quadricepstendon autograft. Stratification will be based on age (18-25 and >25), level of sport activities (Tegner Activity Level Scale 5-7 and 8-10) and surgeon.
Follow-up identical to the follow-up of standard care, with standard checkups after 6 weeks, 6 and 12 months, 2 years. Two extra follow-up moments (after 5 and 10 years) will be planned.

Intervention

Patients who are included in this study will be randomly assigned for ACL reconstruction with one of the three grafts: hamstring autograft, patella autograft or quadriceps autograft. Stratification will be based on age (18-25 years old and >25 years old), surgeon, and on level of activity (Tegner score).

Study burden and risks

Both the surgery and the rehabilitation will be conducted according to the standard protocol of the two hospitals. Participation in this study does lead to extra risk. Relevant risks for patients are the standard risks of an ACL reconstruction. These will be the same for patients that do not participate in this study. All grafts have specific risks and benifits, as described in Chapter 1 of the protocol "Introduction and rationale". Patients are informed and educated about these risks and benifits by the orthopaedic surgeon, prior to the choice of participation in this study. The benefits of each graft surpass the potential risks for said graft in all three graft types.

This study focussus on the evaluation of three types of surgical treatment. Therefore, this study can only be conducted with patients who require such an intervention.

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

• Patients active in sports, Tegner =/>5
• Primary ACL rupture, evident from anamnesis (acute trauma, snapping sensation, swelling within several hours, feeling of instability), physical examination (positive Lachman test, anterior drawertest and/or pivot shift test), radiograph and MRI
• Willing to comply to the suggested (nationwide standard) rehabilitation protocol, supervised by a NFVS registerd sport-physical therapist
• <6 months between initial trauma and surgery

Exclusion criteria

• History of knee surgery on the same side
• History of tendon removal on the same side
• Accompanying ligament injury of the knee, evident from anamnesis, physical examination, radiograph and MRI, defined as an ACL rupture in combination with a posterior cruciate ligament or collateral ligament injury,
• Peroperative discovery of cartilage damage; larger than 2cm2 and more than 50% depth
• Peroperative discovery of meniscus injury which requires a meniscectomy of more than 20% or meniscus sutures
• Osteoarthritis of Kellgren and Lawrence grade 2 or more, as evident from the radiograph
• Severe malalignment of the leg
• Tendency to form excessive scar tissue, such as arthrofibrosis
• Muscular, neurological or vascular anomalies that influence healingtime or rehabilitation
• Infection

• Known hypersensitivity to any of the used materials
• Long term relevant medication use such as prednisolone or cytostatics
• Pregnancy at the time of inclusion or surgery
• Known osteoporosis

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-03-2017
Enrollment:	439
Type:	Actual

Ethics review

Approved WMO Date:	14-10-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-08-2018
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
CCMO	NL52749.044.16
Other	trialregister