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Comparing two surgical techniques for anterior cruciate ligament (ACL) reconstruction

Submission date
28/11/2019

Recruitment status
Suspended

Registration date
21/01/2020

Overall study status
Completed

Last Edited
05/08/2020

Condition category
Surgery

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The anterior cruciate ligament (ACL) connects the femur (thighbone) to the tibia (shinbone) and crosses the knee joint. The ACL can get torn when a person changes direction suddenly or twists their knee. A torn ACL is a common sports-related injury and it can prevent participation in sports if it is not repaired. ACL reconstruction is a well-recognised and commonly performed procedure by knee surgeons across in the world. Standard ACL reconstruction using both hamstring muscle tendon grafts was the most commonly performed and has shown good long-term results.
The researchers have recently adopted a new technique of ACL reconstruction into their practice that is called 'all-inside ACL reconstruction'. This is a well-recognised technique and has been performed by knee surgeons during the last 5 years. The researchers have been performing ACL reconstruction with this technique for the last 4 years. All-inside ACL reconstruction technique uses a single hamstring tendon graft due to its unique feature of creating short bony tunnels in the tibia and femur, compared to the standard technique which requires two hamstring tendon grafts.
In recent studies these two techniques have shown similar results at 2-year follow up.
Reduction in hamstring strength is a known problem after harvesting hamstring tendon grafts. Poor hamstring strength leads to subsequent muscle strength imbalance between your back thigh muscles (hamstrings) and front thigh muscles (quadriceps). This causes alterations in hamstring: quadriceps strength ratio which is the most important determinant of ACL graft rupture and failure of the ACL reconstruction. Stronger hamstring strength will certainly have better outcomes.
Since all-inside ACL technique requires harvesting a single hamstring tendon for ACL reconstruction this should potentially cause less hamstring weakness, than harvesting of both hamstring tendons in the standard ACL reconstruction technique. This trial aims to investigate whether there are differences in muscle strength imbalance between these two ACL reconstruction techniques.

Who can participate?
Patients aged between 18 to 50 years and undergoing ACL reconstruction without requiring any other ligament repair or reconstruction of the same knee.

What does the study involve?
A computer will randomly allocate patients who have consented to participate into one of two groups. One group will receive ACL reconstruction using the all-inside technique and the other group will receive ACL reconstruction using the standard medial portal technique. Patients will be asked to assess their pain three times a day for 2 weeks after surgery. After surgery they will follow the normal rehabilitation process, with specialist physiotherapists and will be asked to return to hospital to see their surgeon as normal at 6 weeks, 3 months, 8 months and 24 months. At these follow-up visits, the researchers will perform some extra tests and questionnaires to see how the knee is healing. Patients will be followed up by a physiotherapist until they have gained the required strength in their knee and it has healed sufficiently. This could take up to 1 year.

What are the possible benefits and risks of participating?
The researchers perform these two techniques on a routine basis in their standard practice. There are no added benefits or risks of being in the trial apart from the general risk factors of an ACL reconstruction procedure. Participants will not receive any expenses or payments for being involved in the study. They will not attend any extra appointments apart from the routine follow-ups.
A participant can withdraw from the study at any time, without this having any effect on their medical care. Information collected may still be used.

Where is the study run from?
Queen Elizabeth Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2018 to August 2021

Who is funding the study?
University Hospitals Birmingham NHS Foundation Trust (UK)

Who is the main contact?
1. Mr Tanweer Ashraf (consultant knee surgeon), tanweer.ashraf@nhs.net
2. Mr Shanaka Senevirathna (senior knee fellow), shanakasenevirathna@nhs.net
3. Mr Michael Jubb (specialist musculoskeletal physiotherapist), Mick.jubb@uhb.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mr Shanaka Ravindra Senevirathna

ORCID ID
http://orcid.org/0000-0002-9981-5343

Contact details
Queen Elizabeth Hospital
Mindelson Way
Birmingham
United Kingdom

B15 2GW
+44 (0)7795821682
shanakasenevirathna@nhs.net

Type(s)
Scientific

Contact name
Mr Tanweer Ashraf

Contact details
Queen Elizabeth Hospital
Mindelson Way
Birmingham
United Kingdom
B15 2GW
+44 (0)1213714946
tanweer.ashraf@nhs.net

Type(s)
Scientific

Contact name
Mr Yasir Ashraf

Contact details
Imperial College London
London
United Kingdom
-
-
Sya12@ic.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
260009

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 260009

Study information

Scientific Title

Anatomic medial portal vs all inside arthroscopic ACL reconstruction: a randomised controlled trial comparing hamstring strength and functional outcome

Acronym
ACLRCT

Study objectives
Hypothesis:
Bilateral difference of hamstring to quadriceps to strength ratio should be similar in both groups.

Background:
ACL reconstruction is a well-recognised and commonly performed procedure by knee surgeons across the world. All-inside ACL reconstruction technique is a new development which is getting more popular due to its unique features of closed socket tunnels, dual suspensory graft fixation, decreased bone removal and smaller skin incisions. As per recent studies, all-inside ACL appears to have similar overall results on subjective and objective outcomes studies compared to standard medial portal ACLR techniques and may be associated with decreased post-operative pain. No significant difference was found between the two groups for IKDC, VAS pain score, Lysholm and Tegner scores at 2years of follow-up.

The all-inside ACL technique typically utilizes a single quadruple semitendinosus tendon autograft, in contrast to standard medial portal ACL technique which typically utilize both semitendinosus and gracilis (S-G) tendon autografts. Since closed femoral and tibial sockets are drilled rather than full tunnels, a decreased graft length is necessary for the all-inside ACL technique. Therefore, a single hamstring tendon harvest provides sufficient length to serve as the autograft when quadrupled.

In our routine practice we perform both the all-inside technique as well as the standard medial portal arthroscopic ACL reconstruction using hamstring grafts. The all-inside technique is performed harvesting a single semitendinosus graft and standard medial portal technique is carried out after harvesting both semitendinosus-gracilis grafts. Patients are followed up by the operating surgeon at 6 weeks, 3 months and 8 months following surgery. They will be clinically assessed for wound healing, stability and range of movements. Functional outcome will be assessed with IKDC (International Knee Documentation Committee) scores.

Post operatively both groups follow a standard agreed protocol for rehabilitation under specialised musculoskeletal physiotherapists. All our patients will undergo isokinetic dynamometer measurement between 4th and the 6th month during the rehabilitation phase to determine the difference of hamstring to quadriceps strength ratio to the normal side, which is an important parameter to be assessed before returning to sports following ACL reconstruction. They will also be assessed on Hop testing and isokinetic dynamometer measurement of the Hip muscle strength.

The hamstring muscles act as agonists to the ACL by resisting the anterior tibial displacement those results from quadriceps muscle forces at the knee. Neuromuscular imbalance with low hamstring to quadriceps strength ratio has been identified as a risk factor for ACL graft in terms of rupture. The maximum acceptable bilateral deficit of H:Q strength ratio will be 10-15% before returning to sports following ACL reconstruction.

Harvest of a single hamstring tendon for reconstruction with the all-inside ACL technique should potentially cause less functional deficits than harvest of both S-G hamstring tendons in standard ACL technique. Therefore difference of H:Q strength ratio should remain low following all inside

ACLR in comparison to standard technique, which may enable early return to sports and reduce the risk of graft re rupture.

Since there remains a need for a methodologically sound RCT, we have decided to conduct the current trial to compare difference in the Hamstring to Quadriceps strength ratio in these two groups of patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending

Study design
Single-centre randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Anterior cruciate ligament (ACL) reconstruction using two different surgical techniques

Interventions
Randomisation process:
Patients are randomised into two groups using a computer-based randomization technique. Patients in group A will undergo anterior cruciate ligament reconstruction (ACLR) using the all-inside technique and patients in group B will undergo ACLR using the standard medial portal technique. Both procedures are performed arthroscopically.

The all-inside ACL technique typically utilizes a single quadruple semitendinosus tendon autograft, in contrast to standard medial portal ACLR technique which typically utilizes both semitendinosus-gracilis (S-G) tendon autografts. Harvest of a single hamstring tendon for reconstruction with the all-inside ACL technique should potentially cause less functional deficits than harvest of both S-G hamstring tendons in standard ACL technique. Therefore difference of H:Q strength ratio should remain low following all inside ACLR in comparison to standard technique, which may enable early return to sports and reduce the risk of graft rupture.

Following ACL reconstructions, participants will be followed up as usual by the operating surgeons at 6 weeks, 3 months, 9 months and 18 months. International Knee Documentation

Committee (IKDC) and Return to Sports Index (RSI) questionnaires will be filled at each follow-up visit. The IKDC score is a knee-specific patient-reported outcome measure. It's considered to be one of the most reliable outcome reporting tools in its category and was one of the instruments used in the popular MOON study. IKDC has been subjected to rigorous statistical evaluation and has proven to be a valid and responsive patient-reported outcome measure (PROM). The RSI score will be used to inform the decision-making process with regards to the participant being able to participate in contact/pivoting sports.

Patients will have isokinetic dynamometer measurements taken by the musculoskeletal physiotherapist to assess hamstring:quadriceps (H:Q) strength ratio and hip muscle strength 6 months after surgery. Patients will also undergo hop testing after 6 months. Hop tests are often utilized by rehabilitation specialists to determine an athlete's ability to generate and dissipate a force when compared to their contralateral knee. They include single leg hop for distance, triple hop for distance, and crossover hop for distance. Limb Symmetry Index will be calculated to compare the involved and uninvolved side. Using these tests can help the physiotherapist to make decisions on discharging patients safely back to sports.

Pain will be assessed using a visual analogue scale (VAS) will be done on the day of surgery, prior to discharge by the physiotherapist, and the patient will be asked to maintain a diary for the first 2 weeks.

Data collection will be done revealing recorded IKDC scores, Isokinetic dynamometer measurements and physio records during the follow up visits. These data will be collected using Case Report Forms (CRFs). These will be stored securely in the NIHR SRMRC

Intervention Type
Procedure/Surgery

Primary outcome measure
Hamstring:quadriceps (H:Q) strength ratio measured using an isokinetic dynamometer at 6 months after surgery

Secondary outcome measures
1. Patient's assessment of knee function assessed using the International Knee Documentation Committee (IKDC) questionnaire at 6 weeks, 3 months, 9 months and 18 months post-surgery
2. Psychological readiness to return to sport after anterior cruciate ligament (ACL) injury and reconstruction surgery assessed using the Anterior Cruciate Ligament Return to Sport After Injury (ACL-RSI) questionnaire at 6 weeks, 3 months, 9 months and 18 months post-surgery
3. Knee function assessed using hop testing (single hop distance, triple hop distance and crossover hop distance) at 6 months post-surgery
4. Limb symmetry assessed using Limb symmetry Index (LSI) at 6 months
5. Hip muscle strength assessed using an isokinetic dynamometer at 6 months post-surgery
6. Hip muscle stability assessed at 6 months by clinical examination checking for proximal hip muscle strength, followed by hop testing.
7. Early graft failure assessed assessed as per patient's symptoms and clinical examination during each visit with the surgeons and physiotherapists.
8. Post-operative pain assessed using a visual analogue scale (VAS) on the day of surgery, prior to discharge by the physiotherapist, and the patient will be asked to maintain a diary scoring pain three times daily for the first 2 weeks
9. Length of operating time recorded in the operating notes
10. Grade of surgeon recorded in the operating notes

Overall study start date
28/09/2018

Completion date
01/05/2022

Eligibility

Key inclusion criteria
1. Aged 18-50 years
2. Undergoing ACL reconstruction following traumatic injury

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Multiligamentous injury
2. Patient declines participation or lacks capacity to consent
3. Pregnant
4. Prisoner

Date of first enrolment
01/02/2020

Date of final enrolment
01/08/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
University Hospitals Of Birmingham NHS Trust
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust

Sponsor details
University Hospitals Birmingham
R & D Office
Birmingham
England
United Kingdom
B15 2TH
+44(0)1213714185
r&d@uhb.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.uhb.nhs.uk/research.htm

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals Birmingham NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Publication Policy:
Results will be published in appropriate peer-review journals and presented at relevant scientific meetings. All participants shall receive a short report of the study findings if requested.

Archive Plan:
All essential study documentation will be archived in the Trust archiving facility for a period of 15 years.

Intention to publish date
01/08/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.0	28/07/2019	05/02/2020	No	Yes