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The ACL Repair vs Reconstruction Study (ACL STARR)

Submission date
24/01/2025

Recruitment status
Recruiting

Registration date
30/01/2025

Overall study status
Ongoing

Last Edited
09/01/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The knee is the most injured joint. The Anterior Cruciate Ligament (ACL) is an important band of tissue that supports the knee. It is a strong structure in the centre of the knee which attaches the femur (thigh bone) to the tibia (shin bone). It is often injured during manual work or sports. Injury to the ACL can lead to the knee becoming unstable, giving way and a loss of confidence. An unstable knee can cause damage to other parts of the knee such as the cartilage or meniscus (shock absorbers), which can lead to osteoarthritis (OA) developing in later life.
There are different surgical options for people with an ACL injury. The most common is reconstruction, which uses tissue from other parts of the body, such as the hamstrings, to act as a replacement. This is a successful operation but does involve damage to bones from drilling holes, removal of tissue from elsewhere in the body, and does not keep any of the torn ligament which has potentially useful nerve endings. An alternative approach is to reattach the original ligament back from where it has torn in a “repair” rather than reconstruction. By preserving the ligament, avoiding tissue harvest and drilling smaller holes in the bone, ACL repair could provide faster recovery, better medium to long term stability, and might reduce likelihood of OA in the future. Older versions of ACL repair techniques have not worked well enough, but newer techniques are available, and this may now make repair a viable option.

Modern ACL repair (stitching) is relatively new and, despite clear potential, has not been fully evaluated. It remains unknown whether it confers any of the theoretical benefits. We aim to conduct a comparative study to find out which is the best technique, reconstructing the ligament or repairing it. The research question is: For patients with recent proximal ACL ruptures (where the ligament has pulled directly off the bone), is ACL repair superior to ACL reconstruction at 24 months post-surgery? This will be measured by a questionnaire relating to the knee called KOOS-4.

A special type of study called a randomised controlled trial is needed to answer this question. This involves assigning participants to different treatments using a process called randomisation so the effects of each treatment can be compared fairly.

Who can participate?
People who have injured their ACL, who may be suitable for either operation, will be invited to join the study.

What does the study involve?
Participants will be randomly allocated to one of the two types of ACL surgery.
ACL REPAIR: this group will have surgery to repair the ACL, with the ligament being stitched back onto the bone.
ACL RECONSTRUCTION: this group will have surgery to reconstruct the ACL. This will involve replacing the torn ACL with other tissue from their body to act as a replacement.
Participants will be asked to complete a pain score at 3 and 6 weeks after surgery. Then they will be asked to complete questionnaires relating to their knee at 6-, 12- and 24-months post-surgery. Participants will be able to complete questionnaires electronically or on paper according to their preference.

What are the possible benefits and risks of participating?
We do not know whether one of these operations will be better for patients than the other. We hope that by comparing them, we will gather evidence to show which surgical option is better.
Both surgical procedures are designed to help reduce the symptoms people experience.
There are risks associated with both ACL repair and reconstruction surgery, such as re-rupture or graft failure.
Other risks associated with these surgeries include pain, infections, tendon, ligament or nerve damage, scars, blood clots and swelling. These are the same risks for patients who do not take part in the study and decide to have ACL surgery. The risks will be discussed in detail with participants by the clinical teams looking after them in hospital.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2024 to Dec 2029

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
1. Associate Professor Stephen McDonnell: sm2089@cam.ac.uk
2. Jenny O’Callaghan/ Nick Beale: acl_starr@ndorms.ox.ac.uk

Contact information

Type(s)
Public

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Type(s)
Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
317530

Central Portfolio Management System (CPMS)
53259

National Institute for Health and Care Research (NIHR)
157938

Study information

Scientific Title
Anterior Cruciate Ligament Stratified Accelerated Repair or Reconstruction Single blind randomised controlled trial for patients with proximal ACL injuries treatment with ACL repair v ACL reconstruction (ACL STARR)

Acronym
ACLSTARR-UK

Study objectives
In patients with recent proximal ACL ruptures, ACL repair is superior to ACL reconstruction at 24 months post intervention

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/01/2025, East of England- Cambridge South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8084; cambridgesouth.rec@hra.nhs.uk), ref: 25/EE/0016

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anterior cruciate ligament injuries

Interventions
The ACL STARR study is a randomised controlled trial. Participants will be allocated to either repair or reconstruction surgery at random using a computer. This will enable us to find out which treatment is best by making a fair comparison.

A two-way superiority design has been chosen, which means that we can show if one treatment method is better than the other for this patient group. If ACL repair is better than ACL reconstruction, it provides evidence to enable its wider use in clinical practice. If reconstruction is better than ACL repair, then ACL repair should not be used except in specific circumstances. This will improve treatment for patients for whom there is currently uncertainty and variable practice.

The study sample size is 214 participants (107 in each group) with acute proximal tears of the ACL (a complete tear of the ACL where the ligament has pulled off the bone). Participants will be identified and recruited following a routine MRI scan which identifies the tear pattern. Potential participants must have undergone shared treatment decision-making discussions with their clinical team and have decided on having surgery over non-surgical treatment (physiotherapy) for their ACL injury.

BASK has categorised ACL repair as a 'priority 2 procedure', meaning that ideally, surgery should be performed within 4 weeks. This trial specifies that surgery (for both repair and reconstruction) is undertaken no more than 50 days post-injury. This timeframe means that repair surgery is more likely to be successful, while keeping in mind the current pressures on NHS waiting lists.

For those participants who consent to take part, we will collect baseline information including demographic data and baseline questionnaires relating to their knee and mental wellbeing. Randomisation will be performed during surgery after the surgeon has assessed the ligament. Participants will be randomised to have either ACL repair or ACL reconstruction. We anticipate 25% of those who consent will be deemed unsuitable for repair during surgery. These participants will have reconstruction surgery and will not continue in the trial. Participants will be recruited from approximately 20 sites in the UK. Both our adult and young people PPI groups felt that as long as both surgeries were safe, randomisation in theatre would be acceptable.

Following surgery, all participants will be referred and undergo physiotherapy with a senior physiotherapist with experience of ACL injuries, which follows the routine care treatment pathway. Post-operative pain scores will be collected at 3 and 6 weeks, and questionnaires relating to the knee and participant wellbeing will be collected at 6, 12, and 24 months post-surgery with the primary outcome of KOOS-4 (knee function questionnaire) at 24 months. Our PPI groups helped us choose our questionnaires, based on the outcomes which are most important to them (post-operative pain, mental wellbeing, and return to work and sport). They feel that our outcomes are reasonable and would be happy to complete the series of questionnaires at home, particularly as they wouldn't want extra clinic visits following discharge from physiotherapy.

We have embedded an internal pilot into the study, which will take place in 9 UK sites over a period of 10 months. The overall patient recruitment target for this internal pilot phase will be 28 randomised patients. Stop-go criteria will be reviewed after 10 months of recruitment.

We also plan longer-term follow-up at 5 years post-randomisation, from registry data, if additional funding is obtained. A mirror study funded by the NHMRC (conducted to the same core protocol) will be undertaken in Australia coordinated within the NHMRC Clinical Trials Centre (CTC), Sydney. This will be conducted and reported separately from ACL STARR, with a view to combining de-identified data for a meta-analysis, subject to additional funding.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Knee Injury and Osteoarthritis Outcome Score (KOOS-4) questionnaire at baseline and 24 months post surgery

Key secondary outcome(s))
1. KOOS score is measured using KOOS 5 Questionnaire at 6, 12, and 24 months after randomisation
2. Resource use data is measured using Health Economics Questionnaire and EQ-5DL & -VAS Questionnaire at 6, 12, and 24 months after randomisation
3. Emotional functioning is measured using Emotional Functioning Questionnaire at baseline, 6, 12, and 24 months after randomisation
4. Surgeon confidence is measured using Surgery Case Report Form on the day of surgery

5. Post-operative pain score is measured using Pain NRS at 3 and 6 weeks after randomisation
6. Time to return to sport is measured using Modified Tegner Questionnaire and Tegner Questionnaire at baseline, 6, 12, and 24 months after randomisation
7. Patient satisfaction is measured using Patient Satisfaction Questionnaire at 12 and 24 months after randomisation
8. Intervention-related complications are measured using Health Economics Questionnaire and Case Report Form at 6, 12, and 24 months after randomisation
9. Objective evidence of graft/repair failure is measured using Case Report Form up to 24 months after randomisation

Completion date
31/12/2029

Eligibility

Key inclusion criteria
1. Patients aged 14 years and above
2. Willing & able to provide informed consent and comply with study procedures
3. Proximal ACL tear pattern suitable for both repair or reconstruction
4. Willing to accept either study arm allocation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
14 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. History of major knee surgery: Have had previous knee surgery (other than diagnostic arthroscopy or partial meniscectomy) to the index knee
2. Concomitant severe injury to the contra-lateral knee
3. High grade multi ligament injury: High grade injuries to other ligaments (i.e. medial collateral, lateral collateral, posterior cruciate) in the knee (Grade > 2)

Date of first enrolment

03/07/2025

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
England
S10 2TH

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital

Clifford Bridge Road
Coventry
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CV2 2DX

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford
England
OX3 7LD

Study participating centre
Lanarkshire University Hospitals
Kirklands
Fallside Road
Bothwell
Glasgow
Scotland
G71 8BB

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
England
NE29 8NH

Study participating centre
North Bristol NHS Trust
Southmead Hospital

Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
Sandwell & W Birmingham NHS Trust
City Hospital
Dudley Road
Birmingham
England
B18 7QH

Study participating centre
Betsi Cadwaladr University Lhb
WREXHAM MAELOR HOSPITAL
Wrexham
Wales
LL13 7TD

Study participating centre
The Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
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England
SY3 8XQ

Study participating centre
NHS Ayrshire and Arran
Ailsa Hospital
Dalmellington Road
Ayr
Scotland
KA6 6AB

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield

England
S5 7AU

Study participating centre
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Gobowen
Oswestry
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SY10 7AG

Study participating centre
Queens Medical Centre
Nottingham University Hospital
Derby Road
Nottingham
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NG7 2UH

Study participating centre
Salisbury District Hospital
Odstock Road
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SP2 8BJ

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NP20 2UB

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan

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	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes