

The ACL Repair vs Reconstruction Study (ACL STARR)

Submission date 24/01/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/01/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/01/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Study website

<https://www.aclstarr.com>

Contact information

Type(s)

Public

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Type(s)

Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

317530

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 53259, NIHR157938

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

To follow

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 measure

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

Secondary outcome measures

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

Overall study start date

01/05/2024

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

Age group

Mixed

Lower age limit

14 Years

Sex

Both

Target number of participants

Planned Sample Size: 286; UK Sample Size: 286

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

01/03/2025

Date of final enrolment

30/06/2027

Locations

Countries of recruitment

England

Scotland

United Kingdom

Wales

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Addenbrookes Hospital

Hills Road

Cambridge

United Kingdom

CB2 0QQ

Study participating centre

Sheffield Children's NHS Foundation Trust

Western Bank

Sheffield

United Kingdom

S10 2TH

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital

Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
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CV2 2DX

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
Headington
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United Kingdom
OX3 7LD

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

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

Study participating centre

Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre

North Bristol NHS Trust

Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre

Sandwell & W Birmingham NHS Trust

City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre

Betsi Cadwaladr University Lhb

WREXHAM MAELOR HOSPITAL
Wrexham
United Kingdom
LL13 7TD

Study participating centre

The Shrewsbury and Telford Hospital NHS Trust

Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre

Kings College Hospital

Denmark Hill

London
United Kingdom
SE5 9RS

Study participating centre

Worcestershire Acute Hospitals NHS Trust

Worcestershire Royal Hospital
Charles Hastings Way
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United Kingdom
WR5 1DD

Study participating centre

NHS Ayrshire and Arran

Ailsa Hospital
Dalmellington Road
Ayr
United Kingdom
KA6 6AB

Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust

Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

Sponsor details

Cambridge Biomedical Campus, Hills Road
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CB2 0QQ
+44 1223 217418
cuh.research@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.cuh.org.uk/>

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Publication and dissemination plan

The findings will be published in a high impact peer-reviewed journal and will be disseminated across the surgical community, the wider medical community and NICE. Study papers will be published in high impact factor journals and will be made available under open access so that high visibility of the work will be maintained as per the NIHR policy.

Intention to publish date

31/12/2030

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date