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ACL STARR-UK Study: Anterior Cruciate Ligament Repair or Reconstruction?

Chief Investigator: Associate Professor Stephen McDonnell

PARENT/GUARDIAN | PARTICIPANT INFORMATION SHEET

We would like to invite your child to take part in a new research study called ACL STARR.

The aim of the study is to compare two different surgical techniques for repairing a torn Anterior Cruciate Ligament (ACL), to see if one is better than the other.

Before you decide, it is important for you and your child to understand why this research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. If anything is unclear, or if you would like more information, please ask a member of the team who approached you about this study.

This leaflet explains why we are doing this research, what the study will involve and exactly what being in the study would mean for your child. This is to help you, and your child decide whether they would like to take part.

An explainer animation video is available to watch by clicking here. <add link>

What is the purpose of ACL STARR?

The knee is the most commonly injured joint. The 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).

The ACL is often injured during manual work or sports. Injury to the ACL can lead to the knee becoming unstable, giving way, and people may experience a loss of confidence in their knee. 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.

ACL injuries can be treated with either surgery or rehabilitation. You and your child will decide, together with your child's surgeon, whether your child will have non-surgical treatment (rehabilitation physiotherapy), or surgery followed by physiotherapy.

The ACL can be injured in several ways, one type of injury is a tear to the ligament close to the point where ligament attaches to the bone, this is called a proximal tear. We are inviting your child to take part because they have a proximal tear to their ACL and have, following discussion with you and their surgeon, decided to undergo surgical treatment.

There are two surgical options for treating people with a proximal ACL tear (see Figure 1):

Reconstruction	Repair
The most common operation for a torn ACL is **reconstruction**, which uses tissue from other parts of the body, to act as a replacement (graft). This is usually done by keyhole surgery. The surgeon will create a tunnel through your upper shin bone and lower thigh bone and thread the graft through the tunnel and fix it in place. This operation is well tried and tested.	There is another less commonly used option, which involves direct **repair** of the torn ligament. Repair involves re-attaching the damaged ligament back from where it has been avulsed (pulled off). This is less invasive than a reconstruction as there is no graft harvest, and smaller tunnels drilled in the bone, and because you keep your ligament, there is the potential for less pain, and a more normal feeling knee.

There have been research studies already undertaken which show that both surgeries are safe. However, there are no large-scale studies which directly compare the two types of surgery to help us know whether the injury is best treated with reconstruction or repair surgery. A randomised controlled trial is needed to answer this question. This involves assigning participants, at random, to the different treatments so the effects of each treatment can be compared fairly. We hope our study will provide evidence to better inform treatment options available for patients in the NHS. We are recruiting 286 patients ('participants') from several NHS Hospital Trusts across the UK and will compare all the information collected to find out the best treatment to use.

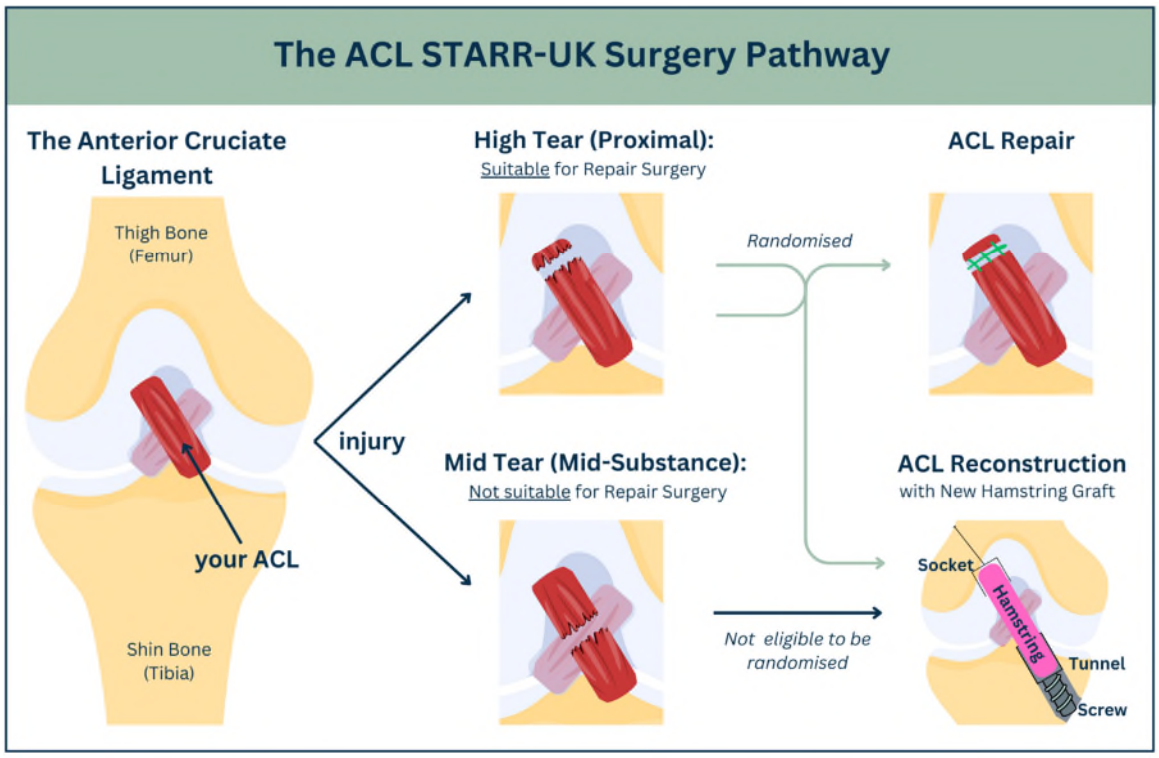

Figure 1. The Surgery Pathway

Does my child have to take part?

No. You and your child should decide whether to take part in this study. Please keep this leaflet and use it to help make your decision. You and your child are free to leave the study at any time without giving a reason. We will collect data from your child up until this point.

Please remember, it is you and your child's decision to take part, either now or if you change your mind during the study, this will not change the standard of the care your child receives. Should you and your child choose not to participate they will continue to be treated under the NHS as before, without a change to their management.

What will happen if my child takes part?

If you and your child are happy to take part in the study, you will be asked to complete a consent form and your child will be asked to complete an assent form, which shows they also give their permission.

When your child turns 16 years of age, we will get in touch with you to ask them for their consent to continue in the study.

A member of the research team will then go through questionnaires with your child relating to their knee, and the clinical team will arrange for your child to come into hospital for surgery.

Once they have had surgery, they will have physiotherapy to help in their recovery. Both groups will have the same care before and after surgery.

We will ask your child to complete pain scores at 3 and 6 weeks after surgery, and some more questionnaires relating to their knee at 6, 12 and 24 months (2 years) after their operation.

What surgery will my child receive?

Your child will have an equal chance (50:50) of receiving either Reconstruction surgery or Repair surgery. The treatment that they are allocated to will be decided at random by a computer. This will be done at the start of the operation, so that the surgeon can look at their ligament and be sure that it is suitable for either surgery.

The surgery will be undertaken as soon as possible, but no longer than 50 days from the date of your child's injury.

We will not be telling people which surgery they have had.

It is important to know that there is a chance that your child could be enrolled in the study, but at the start of their operation, the surgeon finds that their ACL tear is not suitable for both surgeries. If this is the case, your child will not be randomised, and they will have reconstruction surgery. This means they will not continue in the study and will not be asked to complete the follow-up activities (pain scores and questionnaires). They will be looked after as normal after their surgery.

After surgery, your child will have physiotherapy to help with rehabilitation (as part of your child's routine NHS care).

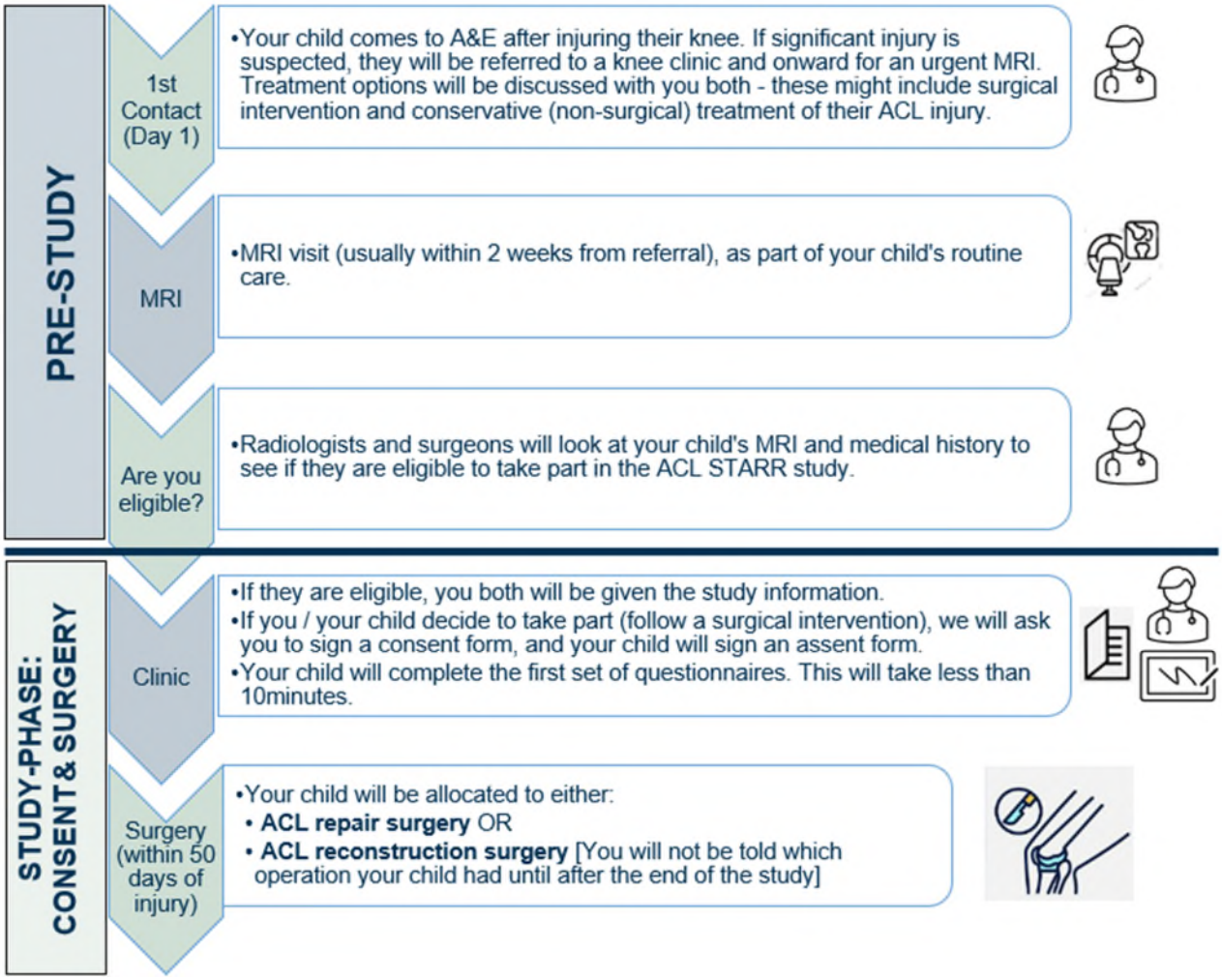

Figure 2. The Participant Pathway: Day 1 to Surgery

What are the risks for my child?

ACL Surgery: There are risks associated with both repair and reconstruction ACL 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 of the operation will be discussed in detail with you and your child by the clinical team looking after you in hospital.

What are the benefits of taking part?

Both operations are designed to help reduce the symptoms your child is currently experiencing in their knee. Both reconstruction and repair are successful treatments, we are doing the study find out if one is better.

If ACL repair is found to be beneficial, it may become more widely used in the NHS in the future to help other young people with ACL injuries.

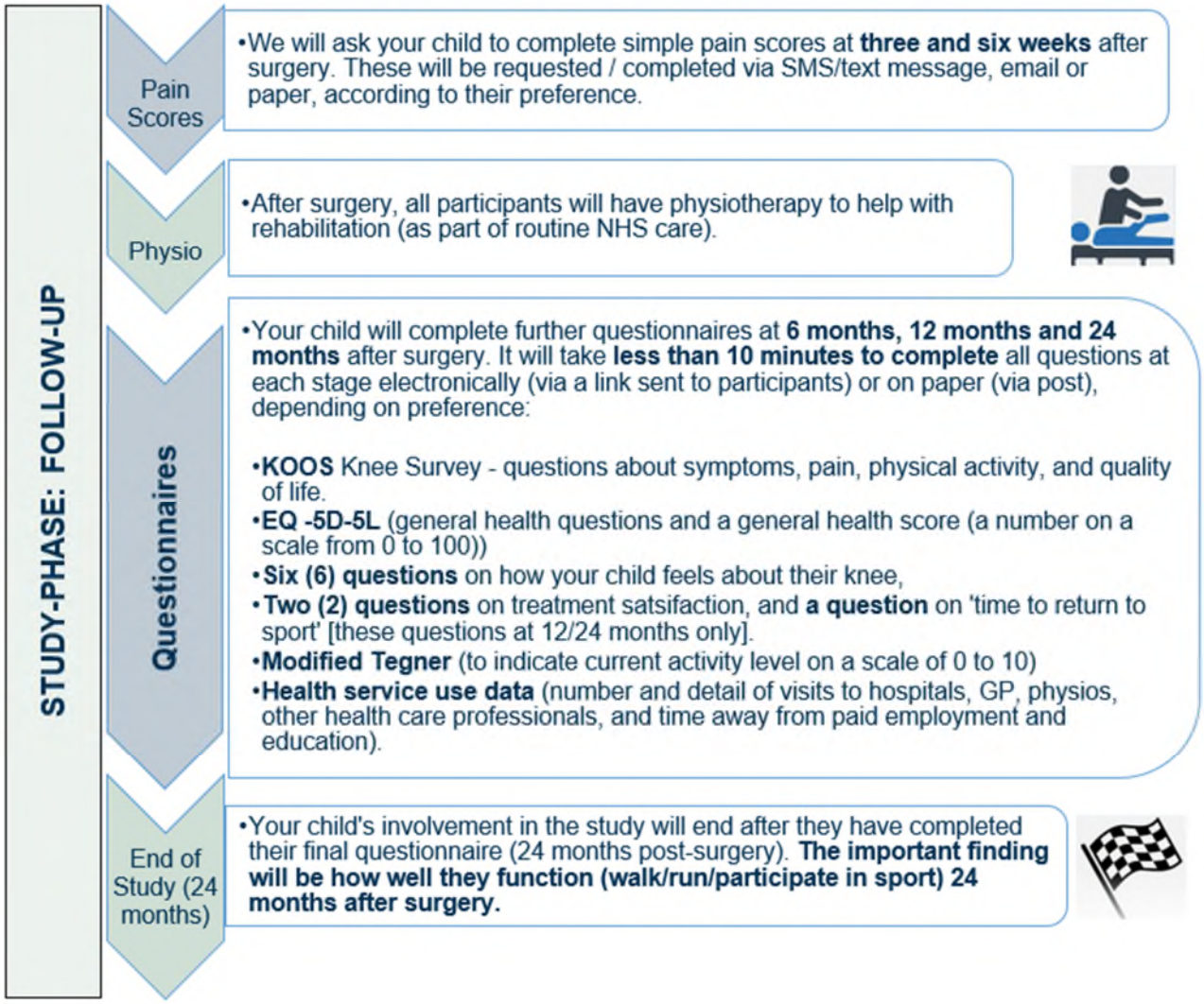

Figure 3. The Participant Pathway: Post-surgery and Follow-up

What if my child decides to withdraw from the study?

Your child can withdraw from the study at any time. You do not need to give a reason, and their medical care or legal rights will not be affected. If you or your child decide to withdraw all information collected up to the date of withdrawal will still be used but no further data will be collected.

Will my child be reimbursed for taking part?

There should be no costs to you/your child for taking part in this research. Appointments at MRI, knee clinic and surgery would be all a part of your child's normal routine care. We ask your child to complete questionnaires from home, via email or prepaid post, and there are no planned additional visits to hospital for this research. If, however, there is a reason your child needs to attend a hospital appointment for research purposes (e.g. a visit to speak further with a clinician about the study before signing an assent form), reasonable travel expenses will be reimbursed. Please visit https://finance.admin.ox.ac.uk/how-to-claim-expenses-claimants-external-to-the-university for details of how to claim travel expenses.

We are giving everyone who takes part in this study a £20 voucher as a thank you gift.

DATA MANAGEMENT

What will happen to the results of this study?

At the end of this study, we will present our findings in medical journals and at medical conferences. Participants will not be identified from any report or publication placed in the public domain. A description and results of this clinical study will be available at https://www.isrctn.com/.

A summary of the results will be made available via the study website: www.aclstarr.com once the results have been published.

How have patients and the public been involved in this study?

We held patient and public involvement (PPI) focus groups to assist us in developing different elements of this study. Together with the groups, we refined the research question, and decided on which questionnaires to collect, based on outcomes that are important to patients (e.g. pain after surgery and a quick return to sports and work). Our focus groups were made up of a diverse range patients from across the UK (most had recovered from ACL injuries). In total, 15 patients provided their input. We also held separate meetings with young people (aged 14-16 years), as this age group are commonly affected by ACL injuries and may also benefit from repair surgery. After this, 10 members of a Cambridge-based PPI panel reviewed this participant information sheet. Thanks to their feedback, we have changed words, removed a section, and improved the layout, to make it easier to understand. We will continue to work with our PPI groups throughout the study.

Please visit the following links to general information about taking part in research:

- https://www.nihr.ac.uk/get-involved/take-part-in-a-study
- https://www.nhs.uk/conditions/clinical-trials/

Who is organising the study?

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge are the sponsors of this study. The Chief Investigator is Associate Professor Stephen McDonnell.

The study is managed by the Surgical Intervention Trials Unit (SITU), a part of the Oxford Clinical Trials Research Unit (OCTRU) at the University of Oxford.

The study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by Cambridge South Research Ethics Committee (REC Reference 25/EE/0016). The Health Research Authority, UK

Independent researchers, patient representatives, each hospital's Research and Development department and your healthcare professional have also reviewed and agreed to support this study.

The study followed a 2-stage application process, with assessments at each stage by the HTA Funding Committee.

How will we (the Sponsors) and the University of Oxford use my child's information?

We will need to use information from your child and their medical records for this research project. After consent, the data we collect will include your:

- child's name,
- NHS number (only if you agree, for long term follow-up),
- date of birth, and
- your contact details,
- contact address,
- contact phone numbers (landline and mobile),
- email address.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research (i.e. sending automated SMS text messages to collect pain scores at 3 weeks and 6-weeks post-surgery). Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

We will use the information to request the completion of post-surgery pain scores (via text message, email, or post), send the follow-up questionnaires and gift voucher (via email or post), and send any reminder messages.

People who do not need to know who you and your child are will not be able to see their name, your name or contact details. Your child's data will have a code number instead.

To be reimbursed for travel expenses, your name, postal address, email address and bank details will be shared with the University of Oxford's Finance team. These details will be securely retained by the Finance team for a period of up to 7 years for audit purposes only and then destroyed. It will not be used by them for any other purpose.

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge are the sponsors of this research and, together with the University of Oxford, are responsible for looking after your child's information. We will keep all information about your child safe and secure by:

- Ensuring all information collected about your child because of their participation in the study is kept strictly confidential.
- Your child's personal and medical information will be kept securely and be treated in the strictest confidence.
- The people who analyse the study information will not be able to identify your child and will not be able to find out your child's name, NHS number or your contact details.
- Only de-identified study data, without any personal information will be published at the end of the study.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

At the end of the study, we will archive your child's study data for **5** years. De-identified data may be shared with other researchers at the end of the study.

How will hospital sites use my child's information?

Your child's hospital will collect information for this research study from your child, their medical records, and their treating clinicians and will pass these details to the University of Oxford (including a copy of their/your signed assent/consent forms, if you have agreed to the optional aspect of consent, i.e. contact about future research studies). Queries may be returned to the site to ensure accuracy of the collected information.

Your child's hospital and the University of Oxford will use your child's name and your contact details to contact your child about the research study, to make sure that relevant information is recorded for their care, and to oversee quality of the study.

Your child's data from their questionnaires will be made available to their local study team at their hospital, in this way their treating health professionals will have full oversight of the data relating to their study participation.

If your child agrees to take part, and they are randomised in the study, their GP surgery will be notified. Your child's hospital will keep identifiable information about your child from this study for 5 years after the study has finished.

International transfers

We will not share data about your child outside the UK for research related purposes during the study. However, we are running a mirror study with our colleagues in Australia. Their study will mirror the one described in this information sheet. This will enable us to collect more data across relevant populations. This means that de-identified results will be shared between the UK and Australia at the end of the study for data analysis. No information will be shared which could identify your child and will not be combined with other information in a way that could identify them.

We will only share the data that is needed.

We will make sure your child's data is protected. Anyone who accesses their data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law.

What are your choices about how your child's information is used?

- Your child can stop being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.
- You have the right to ask us to remove, change or delete data we hold about your child for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree, we will keep your child's personal details (up until they reach 16), and your contact details, for contacting them about future research.

Please follow the links below to find out how the Sponsor organisation(s) handle personal data processed in connection with the study:

- For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: cuh.gdpr@nhs.net
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- For University of Cambridge, please visit: https://www.medschl.cam.ac.uk/research/information-governance/, or email the Information Governance team at: researchgovernance@medschl.cam.ac.uk
- For University of Oxford, please visit: https://compliance.web.ox.ac.uk/individual-rights https://compliance.web.ox.ac.uk/individual-rights or you can find out more about how they will use your information by contacting acl_starr@ndorms.ox.ac.uk

Where can I find out more about how my child's information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- By asking one of the research team
- By sending an email to acl_starr@ndorms.ox.ac.uk
- By visiting http://www.hra.nhs.uk/patientdataandresearch

What if I have concerns?

Cambridge University Hospitals NHS Foundation Trust (CUH) and the University of Cambridge, as the study sponsors, have appropriate insurance in place in the unlikely event that your child suffers any harm as a direct consequence of their participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you or your child have any concerns or wish to complain about any aspect of the way in which they have been approached or treated, or how their information is managed during this study, please speak with the Principal Investigator or a member of the clinical research team.

Principal Investigator	Name: <add> Telephone: <add>
Research/Specialist Nurse	Name: <add> Telephone: <add>

If you would prefer to speak with someone who is not involved in the, then please contact the Patient Advice and Liaison Service (PALS). PALS is a confidential NHS service that can provide you with support for any complaints or queries you have regarding the care you receive as an NHS patient. However, PALS cannot provide information about this research study. Your local PALS team contact details are:

- <insert relevant NHS site phone number>
- <insert relevant NHS site email>

For support in Scotland, please contact the Patient Advice & Support Service (PASS)
PASS national helpline phone number: 0800 917 2127
PASS website (webchat): www.patientadvicescotland.org.uk

For support in Northern Ireland please contact the Patient and Client Council (PCC)
PCC national helpline number: 0800 9170 222
PCC website: www.patientclientcouncil.hscni.net

Contacts for further information:

If, at any time, you would like further information about this study, please contact:

ACLSTARR Study Team,
RCS Surgical Intervention Trials Unit (SITU)
Botnar Research Centre | Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
University of Oxford
Nuffield Orthopaedic Centre, Windmill Road, Headington
Oxford OX3 7HE
07798 571116 | Email: acl_starr@ndorms.ox.ac.uk | Website: www.aclstarr.com

Further details, including the study explainer video animation, can be accessed via the study website: www.aclstarr.com

Thank you for considering your child's participation in this study and for taking the time to read this information sheet.