# Randomised control trial comparing the hamstring strength and functional outcome: Anatomic medial portal Vs All inside arthroscopic ACL reconstruction

## Patient Information Leaflet

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our surgeons will go through the information leaflet with you and answer any questions you have. We'd suggest this should take about 20 minutes. Please ask us if anything is unclear or if you would like more information.

**What is the purpose of the study?**

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.

We have recently adopted a new technique of ACL reconstruction in to our practice which is called 'all-inside ACL reconstruction'. This is a well-recognised technique and has been performed by knee surgeons at University Hospitals Birmingham during last 5 years.

The all-inside ACL reconstruction technique uses a single hamstring muscle graft due to its unique feature of short bony tunnels in the leg bone (tibia) and thigh bone (femur), compared to the standard technique which requires both hamstring tendon grafts.

As per recent studies these two techniques have shown similar results at two year follow up. In our routine practice we perform both all-inside technique as well as the standard ACL reconstruction using hamstring grafts.

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 re-rupture/failure. Stronger hamstring strength will likely have better outcomes.

Since the 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 standard ACL reconstruction technique.

Therefore, imbalance in thigh muscle strength (Hamstring: Quadriceps strength ratio) should be less following all-inside ACL reconstruction in comparison to the standard technique, which may enable early return to sports and reduce the risk of graft re-rupture.

Since there remains a need for better evidence on the all-inside technique, we are conducting this trial by randomly allocating patients into two groups to compare the difference in the reduction of hamstring strength following standard arthroscopic technique Vs all-inside arthroscopic ACL

reconstruction. We will also measure the functional outcomes of these two procedures using validated scoring systems.

**Why have I been invited?**

Because you are aged between 18 to 50 years of age and undergoing ACL reconstruction without requiring any other ligament repair/reconstruction of the same knee.

**Do I have to take part?**

It is up to you to decide to join the study. We will describe the study and go through this information leaflet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

**What will happen to me if I take part?**

Once you agree to take part in the research study, you will be asked to sign a consent form. A computer will then randomly allocate one of two treatments for your surgery:

**Treatment Group A** - ACLR using all-inside technique

**Treatment Group B** - ACL reconstruction using standard medial portal technique

After your surgery we will use a test called the Visual Analogue Scale (VAS) to assess your pain. We will ask you to complete this scoring for up to two weeks post-surgery. One of our team will go through how to complete the questionnaire before you are discharged home.

After your operation, you will follow the normal rehabilitation process, with specialist physiotherapists and you will be asked to return to hospital to see your surgeon as normal at 6 weeks, 3 months, 8 months and 24 months. At these follow-up visits, we will perform some extra tests and questionnaires to see how your knee is healing.

You will be followed up by a physiotherapist until you have gained the required strength in your knee and it has healed sufficiently. This could take up to 1 year.

**Expenses and Payments**

You will not receive any expenses or payments for being involved in the study. You will not attend any extra appointments apart from your routine follow ups.

**What will I have to do? What are the possible disadvantages and risks of taking part?**

We perform these two techniques on a routine basis in our standard practice. There are no added risks or disadvantages being in the trial apart from general risk factors of an ACL reconstruction procedure.

**What are the possible benefits of taking part?**

We cannot promise being in the trial will help you but the information we get from this trial will help us to improve the standards and quality of care for those patients undergoing ACL reconstruction in the future.

**What if relevant new information becomes available?**

It is unlikely that this will happen during the study period but if this does happen your surgeon will tell you and discuss with you whether you should continue in the study.

**What will happen if I don't want to carry on with the study?**

You can withdraw from the study at any time, without this having any effect on your medical care. The data collected may still be used unless you request for us to remove it. Any data that has been anonymised will not be able to be removed from the study results.

**What if there is a problem?**

If you have any concerns you should contact any member of the research team. Please see their contact details at the end of this leaflet.

If you would prefer to speak to an independent person, please contact the Patients Advice and Liaison Service (PALS) on 0121 371 2000.

**Will my taking part in this study be kept confidential?**

Once you have agreed to be involved in the study, you will be allocated a trial specific number, this is how we will refer to you during the study, and we will not use any identifiable information such as your name, address or date of birth.

Any data we collect throughout the duration of the study will be stored securely at the Queen Elizabeth Hospital and will only be viewed by the study team with the exception of authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

**What will happen to the results of the research study?**

The results will be published in orthopaedic journals or presented at conferences. All the information we present will continue to be anonymous. If you wish to be informed of the results of the study, please inform the research staff and we can ensure that this happens at the end of the study once all the information has been analysed.

**Who has reviewed the study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the XXXXX XXXXX (Ref: XXXXXX).

**Research Team Contact Details**

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