

Comparing the JewelACL artificial hybrid graft with a tendon graft for ACL reconstruction

Submission date 03/02/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/02/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/02/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The anterior cruciate ligament (ACL) connects the femur (thigh bone) to the tibia (shin bone) and helps to keep the knee stable. A torn ACL is a common injury in sports where the leg can get twisted, such as football. To replace the torn ACL, a piece of tendon is taken from the patient's leg (hamstring) or knee (patellar tendon) and attached in place within the knee.

There is now an artificial graft called JewelACL(TM) that can be used instead of taking a piece of tendon from the patient. The artificial graft is made of polyester and promotes the patient's own cell growth by providing a scaffold. It is thought that there may be less pain for the patient with hybrid artificial grafts and quicker recovery to exercise than tendon grafts. However, there is not yet enough research to decide which is better. This study aims to compare the two grafts.

Who can participate?

Adults who are scheduled for ACL reconstruction surgery

What does the study involve?

Participants will be randomly allocated to receive a tendon graft or JewelACL. They will receive the ACL reconstruction surgery and aftercare as normal. They will also need to attend some additional appointments where their knee function will be measured and they will be asked about their pain and recovery using questionnaires.

What are the possible benefits and risks of participating?

There are no expected additional benefits or risks to participating in the study.

Where is the study run from?

Northern Care Alliance (UK)

When is the study starting and how long is it expected to run for?

June 2018 to June 2027

Who is funding the study?

Xiros Ltd (UK)

Who is the main contact?
Mr Neil Jain, neil.jain@nca.nhs.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
253318

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 42759, IRAS 253318

Study information

Scientific Title
The Jewel ACL study: Feasibility randomised controlled Trial comparing the outcomes of the auto graft ACL reconstruction (using hamstring tendon) to a hybrid artificial (JewelACL) and autograft ACL reconstruction

Acronym
JewelACL

Study objectives
Current study hypothesis as of 13/02/2024:
This trial will compare an artificial hybrid graft with the patient's own tendon graft for ACL reconstruction. Currently we do not have enough data to suggest which is best. The theory is that there may be less pain for the patient with hybrid artificial grafts and quicker recovery to

exercise than tendon grafts.

The artificial graft is made of polyester and promotes own cell growth by providing a scaffold. The study will last 3 and a half years to allow 18 months of recruitment and 2 years follow up. We will follow up patients in clinic and via questionnaires. This study will be carried out in clinic at NHS hospitals and functional assessment will be carried out at the University of Salford (UoS). All patients over the age of 18 that attend clinic with anterior cruciate ligament rupture will be considered unless it is a revision procedure or the patient has a BMI over 40.

Previous study hypothesis:

This trial will compare an artificial hybrid graft with the patients own tendon graft for ACL reconstruction. Currently we do not have enough data to suggest which is best. The theory is that there may be less pain for the patient with hybrid artificial grafts and quicker recovery to exercise than tendon grafts.

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Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 18/11/2019, London – Surrey REC (Whitefriars, Level 3, Block B, Lewins Mead, Bristol BS1 2NT; +44 (0) 207 104 8376; NRESCommittee.SECOast-Surrey@nhs.net), ref: 19/LO/1429

Study design

Randomized; Both; Design type: Treatment, Device, Psychological & Behavioural, Surgery, Rehabilitation, Active Monitoring, Case-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anterior cruciate ligament (ACL) reconstruction

Interventions

Current interventions as of 13/02/2024:

Each participant will have a near-normal journey through the NHS system when having surgery for ACL reconstruction. They will initially be seen in clinic after the injury by one of the surgeons to diagnose the problem. If they have already been diagnosed by MR scan in the GP scenario it will then be a discussion about the risks and benefits of surgery. Not everyone will want surgery, but people that want surgery will then be recruited in that clinic.

The patient will then discuss the trial with one of the surgeons in clinic and be given the patient information sheet. The patient will then have time to discuss with family and friends. They will

then attend a further orthopaedic clinic to be consented. This will be a 15- to 30-minute extra discussion on normal practice and is therefore research time and inconvenience to the patient.

Once patients are recruited to the study they will be placed in clinic appointments and follow up at the end of NHS clinics to prevent delaying routine care to others. The only extra resources being used will be the time of the surgeons in clinic to complete questionnaires and examine the patients. We expect only 1-2 patients from the trial within a clinic per week. This will not impact the routine care provided in the NHS.

If the patient accepts trial recruitment they will be asked to attend the UoS for research purposes only. This will be to obtain baseline data on function such as gait analysis and muscle strength before the operation. This data is essential to compare to post-operatively. They will be reimbursed for travel costs by the private company Xiros Ltd.

The patient will then go through the usual NHS process for all surgery. They will come to Rochdale Infirmary or Fairfield General Hospital for day case surgery as usual practice. They will randomised to a treatment arm using the online process via www.randomization.com. The operation will be performed as is standard with no extra equipment except the potential artificial graft.

Post Op:
2 weeks

Patients will be reviewed in clinic by the surgeons as is standard practice. They will fill out pain questionnaires which is not routine and research only care. They will also see physiotherapists as standard.

6 weeks

They will see the surgeon and physiotherapist in clinic as routine care. Pain questionnaires will be filled out again for research purposes only.

12 weeks

The patient will be seen in clinic with surgeons and physiotherapists as routine care. As part of research care, they will complete questionnaires for outcome data which will take ~10-15 minutes.

12 weeks UoS visit (outside NHS research care)

The patient will be required to attend the UoS where they will perform the Genourob laxity assessment, undergo knee kinesiography, and numerous functional biomechanical tests. This is research care only but will provide valuable information regarding the differences in outcomes between the hybrid artificial graft and hamstrings graft outcomes. They will have their travel costs covered by Xiros Ltd. This visit will take ~3 hours.

6 months

The patient will be seen by the surgeon and physiotherapist to be assessed clinically as routine care. Research care will then be to fill out questionnaires, which will take an additional ~10-15 minutes.

6 months UoS visit (outside NHS Research Care)

The patient will return to the UoS where they will, again, perform the Genourob laxity assessment, undergo knee kinesiography, and numerous functional biomechanical tests. They will have their travel costs covered by Xiros Ltd. The visit will take ~3 hours.

9 months

The patient will be seen by the the surgeon and physiotherapist as routine practice. They will fill out the necessary questionnaires as research practice again, meaning ~10-15 minutes extra time than usual practice.

9 months UoS visit (outside NHS Research Care)

The patient will return to the UoS to perform the Genourob laxity assessment, undergo knee kinesiography, and numerous functional biomechanical tests. Xiros Ltd. will reimburse their travel costs. The visit will take ~3 hours.

12 months

The patient will be seen by the surgeon and physiotherapist which is standard practice for this surgery. They will fill out the necessary questionnaires which will take ~10-15 minutes.

12 months UoS Visit (Research Care only)

The patient will then be seen at the UoS where laxity measures, knee kinesiography and functional biomechanics will be collected for the final time. They will compare the groups data with pre-op and 3-, 6-, and 9-months post-op data.

18 months

The patient will be contacted via phone or email to fill out questionnaires which is extra research time. This is not routine care.

2 years

The patient will be called at to fill out questionnaires which is extra time also. This is not routine practice.

Previous interventions:

Each participant will have a near normal journey through the NHS system when having surgery for ACL reconstruction. They will initially be seen in clinic after the injury by one of the surgeons to diagnose the problem. If they have already been diagnosed by MR scan in the GP scenario it will then be a discussion about the risks and benefits of surgery. Not everyone will want surgery, but people that want surgery will then be recruited in that clinic.

The patient will then discuss the trial with one of the surgeons in clinic and be given the patient information sheet. The patient will then have time to discuss with family and friends. They will then attend a further orthopaedic clinic to be consented. This will be a 15- to 30-min extra discussion on normal practice and is therefore research time and inconvenience to the patient.

Once patients are recruited to the study they will be placed in clinic appointments and follow up at the end of NHS clinics to prevent delaying routine care to others. The only extra resources being used will be the time of the surgeons in clinic to complete questionnaires and examine the patients. We expect only 1-2 patients from the trial within a clinic per week. This will not impact the routine care provided in the NHS.

If the patient accepts trial recruitment they will be asked to attend the MIHP centre for research purposes only. This will be to obtain baseline data on function such as gait analysis and muscle strength before the operation. This data is essential to compare to post-operatively. They will be reimbursed for travel costs by the private company Xiros Ltd.

The patient will then go through the usual NHS process for all surgery. They will come to Rochdale or Fairfield hospital for day case surgery as usual practice. They will randomised to a

treatment arm using the online process via www.randomization.com. The operation will be performed as is standard with no extra equipment except the potential artificial graft.

Post Op:

2 weeks

Review in clinic by the surgeons as is standard practice. They will fill out pain questionnaires which is not routine and research only care. They will also see physiotherapist as standard.

6 weeks

They will see the surgeon and physiotherapist in clinic as routine care. Pain questionnaires will be filled out again for research purposes only.

12 weeks

The patient will be seen in clinic with surgeons and physiotherapist as routine care. Research care will be added onto this visit to fill out questionnaires and perform the genourob laxity assessment. This will take an extra 15-30 minutes for the patient.

6 months

The patient will be seen by surgeon and the physiotherapist to be assessed clinically as routine care. Research care will then be to fill out questionnaires and perform the Genourob laxity assessment. This will take an extra 15-30 min for the patient.

6 months MIHP visit (outside NHS Research Care)

The patient will then travel to MIHP for further biomechanics functional assessment. This is research care only but will provide valuable information regarding the differences in outcomes between the hybrid artificial graft and hamstrings graft outcomes. They will have their travel costs covered by Xiros Ltd. This will be an extra 1-h session on top of normal practice.

9 months

The patient will be seen by the the surgeon and physiotherapist as routine practice. They will fill out questionnaires and the Genourob assessment as research practice again, meaning 15-30 min extra time than usual practice.

12 months

The patient will be seen by the surgeon and physio which is standard practice for this surgery. They will fill out questionnaires and the Genourob assessment again which is an extra 15-30 min.

12 months MIHP Visit (Research Care only)

The patient will then be seen at MIHP again at to be assessed on functional biomechanics. They will compare the groups data with pre-op and 6 months data.

18 months

The patient will be contacted via phone or email to fill out questionnaires which is extra research time. This is not routine care.

2 years

The patient will be called at to fill out questionnaires which is extra time also. This is not routine practice.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

JewelACL

Primary outcome(s)

Patient's assessment of knee function using the International Knee Documentation Committee (IKDC) Questionnaire at 2, 6, 12, 26 and 39 weeks and 1 year, 18 months and 2 years post-surgery

Key secondary outcome(s)

Current secondary outcome measures as of 13/02/2024:

1. Pain assessed using the short form McGill pain questionnaire on the day of surgery and at 2 and 6 weeks post-surgery
2. Knee laxity assessed using the Genourob device at 3, 6, 9 and 12 months
3. Knee function assessed using 3-dimensional gait analysis at a Salford University laboratory with sensors at 3, 6, 9 and 12 months post-operatively. This will include walking, running, knee bend and hop tests.

Previous secondary outcome measures:

1. Pain assessed using the short form McGill pain questionnaire on the day of surgery and at 2 and 6 weeks post-surgery
2. Knee laxity assessed using the Genourob device at 3, 6, 9 and 12 months
3. Knee function assessed using 3-dimensional gait analysis at a Salford University laboratory with sensors at 6 months and 12 months post-operatively. This will include walking, running, knee bend and hop tests.

Completion date

01/06/2027

Eligibility**Key inclusion criteria**

Current inclusion criteria as of 13/02/2024:

1. Persistent knee instability after ACL rupture that merits surgical intervention and ligament reconstruction
2. Listed at the Northern Care Alliance for routine unilateral ACL reconstruction
3. Aged 18 years and over

Previous inclusion criteria:

1. Persistent knee instability after ACL rupture that merits surgical intervention and ligament reconstruction
2. Listed at Pennine for routine unilateral ACL reconstruction
3. Aged 18 years and over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Current exclusion criteria as of 13/02/2024:

1. Refusal to participate
2. Inability to provide informed consent
3. Inability to answer questionnaires for cognitive reasons
4. Morbidly obese (BMI >40 kg/m²)
5. Patient is unable to attend rehabilitation and clinic appointments at the hospital or at the UoS
6. Revision ACL surgery
7. Previous hamstring injury or harvest procedure

Previous exclusion criteria:

1. Refusal to participate
2. Inability to provide informed consent
3. Inability to answer questionnaires for cognitive reasons
4. Morbidly obese (BMI >40 kg/m²)
5. Patient is unable to attend rehabilitation and clinic appointments at the hospital or at MIHP
6. Revision ACL surgery
7. Previous hamstring injury or harvest procedure

Date of first enrolment

01/01/2024

Date of final enrolment

01/06/2025

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Fairfield General Hospital

Fairfield General Hospital

Rochdale Old Road

Bury

United Kingdom

BL9 7TD

Sponsor information

Organisation

Northern Care Alliance NHS Foundation Trust

Funder(s)

Funder type

Industry

Funder Name

Xiros Ltd

Funder Name

National Institute for Health Research (NIHR) (UK)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Protocol file	version 6.0	11/12/2023	13/02/2024	No	No