ISRCTN91866211 https://doi.org/10.1186/ISRCTN91866211

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

Submission date
03/02/2020

Recruitment status
No longer recruiting

Registration date
12/02/2020

Overall study status
Ongoing

Last Edited
13/02/2024

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
Mr Neil Jain

Contact details
Fairfield General Hospital
Rochdale Old Road
Bury
United Kingdom
BL9 7TD
+44 (0)161 624 0420
neil.jain@nca.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
253318

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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.
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 Manchester Institute for Health and Performance (MIHP). 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.

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet.

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/06/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

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
England

United Kingdom

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

Sponsor details
Salford Care Organisation
Salford Royal Hospital
Stott Lane
Salford
England
United Kingdom
M6 8HD
+44 (0)161 206 7050
RDResearch@nca.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.northerncarealliance.nhs.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/06/2028

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