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Synthetic versus autologous reconstruction of the medial patellofemoral ligament

Submission date
20/10/2016

Recruitment status
No longer recruiting

Registration date
03/03/2017

Overall study status
Completed

Last Edited
14/03/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The medial patellofemoral ligament (MPFL) helps to keep the kneecap in the right position. If the MPFL is torn (ruptured), the knee cap is displaced from its normal position. There are many ways to address the unstable knee cap. One such way is to operate, and there are different procedures that can be performed. One method is to use the patient's own hamstring tendons to restore the knee cap (autologous hamstring graft). An alternative is to use a synthetic mesh to restore stability. Both methods have been successfully used, with good results. However, no study has been done to determine if one method is better than the other. The aim of this study is to address this issue, and compare the short-term results using both of these methods.

Who can participate?
Patients aged 14-25 with MPFL rupture. Only patients with 2 or more dislocations are considered for inclusion.

What is involved from you as a participant?
Participants are randomly allocated to one of two groups. One group undergoes MPFL reconstruction surgery with an autologous hamstring graft. The other group undergoes the same surgery but with a synthetic ligament instead. Participants attend outpatient appointments to track their recovery. Initial follow up is performed at 6 weeks after the operation as per routine follow up. Participants' knees are assessed at 3, 6, 12, 18 and 24 months after the operation by a physiotherapist.

What are the benefits and risks of participating?
The information gathered may help assist and guide what surgical method we use and how we subsequently treat patients. The risks of surgery are no different between the groups, as the surgery is almost identical. Using the patient's own hamstring tendons may slightly increase the duration of the surgery and may result in some additional bruising.

Where is the study run from?
Altnagelvin Area Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2016 to January 2022 (updated 11/08/2020, previously: July 2022)

Who is funding the study?
Western Health and Social Care Trust (UK)

Who is the main contact?
Mr Danny Acton

Contact information

Type(s)
Scientific

Contact name
Mr Danny Acton

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
211907

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS Project ID 211907

Study information

Scientific Title
Synthetic versus autologous reconstruction (Syn-VAR) study for recurrent patellar instability: a prospective randomised pilot study

Study objectives

To compare autologous hamstring medial patellofemoral ligament (MPFL) reconstruction with vastus mediu obliquitus (VMO) advancement against synthetic graft MPFL reconstruction with VMO advancement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees of Northern Ireland, 21/08/2017, ref: ORECNI ID 17/NI /0129

Study design
Randomised control prospective single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Recurrent patellar instability with MRI-proven MPFL injury

Interventions
Patients will be randomised to receive either:
1. MPFL reconstruction with autologous hamstring graft (h-MPFL)
2. Synthetic woven ligament (s-MPFL)
Both are in combination with VMO advancement. Once randomised, the patients will have the procedure explained, and have the option to proceed, or opt out pre-operatively. The operating surgeon will not be blinded to the operative procedure. All operations will be performed by a single soft tissue knee specialist surgeon, using their default surgical technique. The only difference in surgical procedure will be the choice of graft used

Pre-operative clinical assessment will be performed by a registrar or consultant. Pre-operative AP, lateral and skyline view radiographs will be reviewed. Measurements for patella alta will be performed (Insall-Salvati and Gaton-Deschamp indices) and congruence angles will be measured. Pre-operative MRI scans will also be reviewed and Tibial Tuberosity to Trochlear groove (TTTG) distances measured.

Patients will be excluded if they require tibial tuberosity transfer or other osseus reconstructive procedures, or a lateral Z-lengthening procedure, as will the requirement for a multi-

ligamentous knee reconstruction. This aims to keep the study population homogenous for the purposes of direct group comparison.

Initial outpatient follow up will be performed at 6 weeks post-operatively as per routine follow up. Post-operative rehabilitation will be in accordance with departmentally agreed post-operative physiotherapy rehabilitation protocol. Functional score assessment will be performed at 3/6/12/18/24 months post-operatively by an outpatient physiotherapist associated with the study. Validated scoring questionnaires will be performed at each visit, to include Tegner-Lysholm activity scores, Kujala stability scores, and the Banff Patellar Instability Instrument (BPII).

Primary end point will be two years, or MRI-confirmed re-rupture requiring revision surgery.

Patients may opt out upon recruitment, or at any time throughout the study. Data collected at clinical review will be included up to the point of opt out for statistical analysis.

Intervention Type
Procedure/Surgery

Primary outcome measure
Functional outcomes, measured using the Tegner activity scale, Lysholm Score and the Banff Patellar Instability Index Score, pre-operatively followed by post-operative checks at 6 weeks, and then again at 3/6/12/24 months post-operatively

Secondary outcome measures
1. Revision surgery
2. Recurrent dislocation
The timepoints for revision and recurrent dislocation are not specified, as these will be defined by these events occurring in the patient after surgery.

Overall study start date
01/09/2016

Completion date
31/01/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/01/2018:
1. Aged 14-25 years
2. Confirmed medial patellofemoral ligament rupture on MRI
3. Pre-operative AP, lateral and skyline radiographs
4. Unilateral or bilateral symptoms
5. Clinical signs of patellar instabiltity
6. Closed proximal tibial physes
7. Only patients with 2 or more dislocations will be considered for inclusion

Previous inclusion criteria from 08/09/2017 to 29/01/2018:
1. Aged 14-25 years
2. Confirmed medial patellofemoral ligament rupture on MRI

3. Pre-operative AP, lateral and skyline radiographs
4. Unilateral or bilateral symptoms
5. Clinical signs of patellar instabiltity
6. Closed proximal tibial physes

Original inclusion criteria:
1. Aged 14-25 years
2. Confirmed medial patellofemoral ligament rupture on MRI
3. Pre-operative AP, lateral and skyline radiographs
4. Unilateral or bilateral symptoms

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
15 in each arm (total 30)

Total final enrolment
20

Key exclusion criteria
Current exclusion criteria as of 14/02/2018:
1. Patients requiring bony transfer procedures (e.g., tibial tuberosity transfer)
2. Patients requiring a lateral release or Z-lengthening of the lateral structures
3. Patients with lateral compression signs on the skyline radiographs
4. Patients with confirmed multi-ligamentous knee injury
5. Patients with confirmed osteochondral lesions on MRI or plain radiograph pre-operatively
6. Patients who have previously underwent surgery
7. Abnormal hip or hindfoot pathology
8. Excessive femoral anteversion (>30 degrees) and/or excessive external tibial torsion (>40 degrees)
9. Excessive coronal plane deformity
10. Dejour grade C/D trochlear dysplasia
11. Excessive patellar tilt as measured by the Angle or Laurin and Fulkerson Angle methods.
12. Skeletally immature patients
13. Eastablish radiological changes of arthritis
14. Patients with confirmed hypersensitivity to synthetic graft material
15. A TT-TG distance >20mm on MRI/CT

Previous exclusion criteria from 08/09/2017 to 14/02/2018:
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2. Patients requiring a lateral release or Z-lengthening of the lateral structures
3. Patients with lateral compression signs on the skyline radiographs
4. Patients with confirmed multi-ligamentous knee injury
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12. Skeletally immature patients
13. Eastablish radiological changes of arthritis
14. Patients with confirmed hypersensitivity to synthetic graft material
15. Insall-Salvati >1.2, Gaton Dechamp <1.3 or TT-TG >20mm

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2. Patients requiring a lateral release or Z-lengthening of the lateral structures
3. Patients with lateral compression signs on the skyline radiographs
4. Patients with confirmed multi-ligamentous knee injury
5. Patients with confirmed osteochondral lesions on MRI or plain radiograph pre-operatively
6. Patients who have previously underwent surgery

Date of first enrolment
01/10/2017

Date of final enrolment
31/07/2020

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Altnagelvin Area Hospital
Glenshane Road
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United Kingdom
BT47 6SB

Sponsor information

Organisation
Western Health and Social Care Trust

Sponsor details

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00sb42p15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Western Health and Social Care Trust

Results and Publications

Publication and dissemination plan
The results will be published in a medical peer-reviewed journal once the study has completed 2 years. As stated in the study protocol, the information will be kept for 5 years in total, so that patients may be recalled or surveyed at 5 years post-operatively to assess longer term function after both repair methods.

Intention to publish date
31/07/2022

Individual participant data (IPD) sharing plan
Data will be kept on a secure computer account on the trust server, with password access only for the study investigators. This will be kept before being electronically destroyed after completion of the study, in line with local data protection policies. There are no plans to make this freely available in the interests of patient anonymity and confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		14/11/2016	03/03/2017	No	Yes
Protocol article	protocol	03/05/2018		Yes	No
Poster results			14/03/2023	No	No
HRA research summary			26/07/2023	No	No