

# Synthetic versus autologous reconstruction of the medial patellofemoral ligament

|                                        |                                                       |                                                                                                              |
|----------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>20/10/2016   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>03/03/2017 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>20/04/2026       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> 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

**Contact details**  
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## Additional identifiers

**Integrated Research Application System (IRAS)**  
211907

**Protocol serial number**  
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 medii obliquus (VMO) advancement against synthetic graft MPFL reconstruction with VMO advancement.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

## **Primary study design**

Interventional

## **Study design**

Randomised control prospective single-centre study

## **Study type(s)**

Treatment

## **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 osseous 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 (BPPI).

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(s)**

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

**Key secondary outcome(s)**

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.

**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 instability
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 instability
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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

## **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. Establish radiological changes of arthritis
14. Patients with confirmed hypersensitivity to synthetic graft material
15. A TT-TG distance >20mm on MRI/CT

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13. Establish 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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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**

United Kingdom

Northern Ireland

**Study participating centre**

**Altnagelvin Area Hospital**

Glenshane Road

Londonderry

Northern Ireland

BT47 6SB

## **Sponsor information**

**Organisation**

Western Health and Social Care Trust

**ROR**

<https://ror.org/00sb42p15>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Western Health and Social Care Trust

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not expected to be made available

### Study outputs

| Output type                                   | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | protocol | 16/04/2026   | 20/04/2026 | Yes            | No              |
| <a href="#">Protocol article</a>              |          | 03/05/2018   |            | Yes            | No              |
| <a href="#">HRA research summary</a>          |          |              | 26/07/2023 | No             | No              |
| <a href="#">Participant information sheet</a> |          | 14/11/2016   | 03/03/2017 | No             | Yes             |
| <a href="#">Poster results</a>                |          |              | 14/03/2023 | No             | No              |