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Patellar Instability: Physiotherapy or Surgery? (PIPS feasibility trial)

Submission date
20/12/2016

Recruitment status
No longer recruiting

Registration date
22/12/2016

Overall study status
Completed

Last Edited
10/07/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The knee is the largest weight-bearing joint in the body. It is a complex joint where the shin bone (tibia) and thigh bone (femur) meet creating a “hinge”. The kneecap (patella) is a small, triangular shaped bone located in front of the knee joint. It is very important that the patella is in the correct position, as it plays a vital role in helping to bend (flexion) the knee by acting as a “pulley” for the thigh (quadriceps) muscle. Patellar instability is where the patella is displaced, often following an injury. It is an important problem affecting young people, and can be a cause of significant disability. Following a dislocation of the knee joint, anywhere between a half and 70% of patients will go on to suffer with repeated instability symptoms in the knee. The condition typically occurs in a young, active, working population and can be very disabling. This is due to the painful episodes themselves but also because the feeling of instability causes patients to restrict their activity to avoid further pain or dislocation. UK patients with recurrent instability of their patella are typically managed with either physiotherapy or surgery. The choice between the two treatment options is made by the treating clinician and there is no evidence-base on which the clinician can make a judgment about best practice. The aim of this study is to conduct a small study to see if a large study comparing the effectiveness of surgery and physiotherapy in patients with plantar instability is feasible.

Who can participate?
Men and women aged 16 or over who present themselves to the clinics at one of the study centres with recurrent patellar instability (2 or more dislocations, or 1 dislocation with ongoing instability symptoms for more than 6 months to the date of the clinic).

What does the study involve?
Participants are randomly assigned by a computer to one of two groups. Those in the first group receive Personalised Knee Therapy. Participants allocated to this treatments are referred to a qualified physiotherapist who has been instructed in this specific treatment. The package of care has been developed by experts in the field specifically for this trial. This treatment does not add any risks or difficulties in case there is a need for surgical intervention in the future. Participants attend an initial session with the physiotherapist who will assess the participants, the problems they face in daily life and their current strategies for managing their condition, and design a treatment plan specific to them. They assess function and strength at the knee and also assess

trunk (middle body), hip, knee and ankle control. Participants are invited to attend at least 6 sessions over a 3 month period and may be invited to more sessions or for more time if they need it. The initial session may last up to an hour, but other sessions will typically be shorter. The treatment changes over time as participant's legs strengthen or symptoms change. When the course is finished, participants are given instructions and guidance how to maintain the strength and control in their leg. Those in the second group receive surgery. Participants allocated to this treatment are assessed by a surgeon who decides on the best operation of them. All of the operations used in this study have been available on the NHS for over 10 years and there are no new or experimental operations used on participants. Participants in both groups are followed up after 12 months.

What are the possible benefits and risks of participating?
Benefits not provided at time of registration. There are very few risks with Personalised Knee Therapy, although some people may have some muscle soreness for a few days after exercises. There is the risk that further dislocations will happen, but the treatment is designed to prevent these. There are some risks with surgery including blood clots, infection, stiffness and pain, although most people do not have problems. Further dislocations can happen after surgery but these are uncommon.

Where is the study run from?
1. University Hospital of Coventry and Warwickshire NHS Trust (UK)
2. The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Trust (UK)
3. Morriston Hospital (UK)
4. The Bristol Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
April 2016 to January 2019

Who is funding the study?
West Midlands NIHR Clinical Research Network (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AM182016

Study information

Scientific Title
A Feasibility Study into Patellar Instability: Physiotherapy or Surgery (the PIPS feasibility study)

Acronym
PIPS

Study objectives
The aim of this study is to conduct a small study to see if a large study comparing the effectiveness of determine the clinical effectiveness of patellar instability surgery (MPFL reconstruction, with or without tibial tubercle osteotomy) in comparison to best non-operative care (Personalised Knee Therapy) in patients with plantar instability is feasible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Coventry & Warwickshire Research Ethics Committee, 30/11/2016, ref: 16/WM /0456

Study design
Multi-centre randomised feasibility trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Patellar instability

Interventions
Participants will be randomly assigned by a computer to either a surgical arm or a non-operative arm consisting of a Personalised Knee Therapy.

Personalised Knee Therapy: Participants allocated to this treatment will be referred to a qualified physiotherapist who has been instructed in this specific treatment. The package of care has been developed by experts in the field specifically for this trial. This treatment does not add any risks or difficulties in case there is a need for surgical intervention in the future. Participants will attend an initial session with the physiotherapist who will assess the participants, the problems they face in daily life and their current strategies for managing their condition, and design a treatment plan specific to them. They will assess function and strength at the knee and will also assess trunk, hip, knee and ankle control. Participants will be invited to attend at least 6 sessions over a 3 month period and may be invited to more sessions or for more time if they need it. The initial session may be up to an hour, but other sessions will typically be shorter. The treatment will change over time as participant's legs strengthen or symptoms change. When the course is finished, participants will be given instructions and guidance how to maintain the strength and control in their leg.

Surgery: Participants allocated to this treatment will be assessed by a surgeon and they will decide on the best operation. This is likely to be either a MPFL (medial patellofemoral ligament) reconstruction, a tibial tubercle osteotomy, or both. All of the operations used in this study have been available on the NHS for over 10 years and there will be no new or experimental operations used on participants.
A MPFL (medial patella-femoral ligament) reconstruction involves 3 small incisions (around 4 cm each) over the knee, as well as two keyhole scars (around 5 mm). One of the hamstring tendons is used to make a new ligament and is attached to the kneecap (patella) and the thigh bone (femur). This ligament is not tight normally but pulls tight when the kneecap tries to dislocate. The ligament starts to heal after 6 weeks but takes approximately 3 months to heal well. Patients do not usually need to wear a brace after this operation, but this will be decided by the surgeon.
A tibial tubercle osteotomy involves a 10cm vertical incision at the top of the shin, where the patella tendon (the tendon under the kneecap) attaches to the lump of bone that you can feel at the top of your shin bone. A piece of bone approximately 3 cm wide, 2 cm thick and 8 cm long is cut under the tendon and is moved by 5-10 mm. The bone is then fixed back in place using 2 or 3 metal screws. This moves the kneecap into a different position. The bone takes approximately 6 weeks to heal. Patients usually need to wear a brace after this operation, but this will be decided by the surgeon.
Participants assigned to surgery will be seen by a physiotherapist after the operation to help them recover.

Participants in both groups are followed up after 3, 6 and 12 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Norwich Patellar Instability Score (NPIS) at 12 months

Secondary outcome measures
1. The Norwich Patellar Instability Score (NPIS) at baseline, 3 and 6 months.
2. The Banff Patella Instability Index (BPII) at baseline, 3, 6 and 12 months.
3. The Kujala score at baseline, 3, 6 and 12 months
4. The Oxford Knee Score – Activity and Participation Questionnaire (OKS-APQ) at baseline, 3, 6 and 12 months
5. The EuroQol EQ5D (EQ5D-5L) at baseline, 6 weeks and 3, 6 and 12 months

Overall study start date
01/04/2016

Completion date
15/01/2019

Eligibility

Key inclusion criteria
1. Provision of written informed consent
2. Aged 16 or over and has closed growth plates on MRI scans (taken as part of standard clinical care)
3. Two or more patella dislocations, OR 1 dislocation with over 6 months of subjective instability leading up to the time of recruitment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Total final enrolment
19

Key exclusion criteria
1. Patients who are unable to adhere to trial procedures or complete questionnaires
2. Previous entry in the present trial (i.e. for the other leg)
3. Patients with another knee condition that results in instability symptoms (ie cruciate ligament rupture, unstable meniscal tear which has not been treated)
4. Past knee surgery (except for simple arthroscopy with or without lateral release, or previous meniscal surgery)
5. Patients with medial dislocations of the patella. This is an exceptionally rare condition but would be treated differently in both arms if it were to occur.
6. Patients with developmental abnormalities of the lower limb requiring complex surgical intervention. This is because the conditions listed below require complex major orthopaedic procedures which may have a different risk-benefit balance to those in the planned study group,

but are too rare to be included in the study and analysed separately. These include:
6.1. Severe trochlea dysplasia which (in the opinion of the treating surgeon) requires trochleoplasty
6.2. Rotational, coronal or sagittal mal-alignment of femur or tibia which in the opinion of the treating surgeon requires surgical correction (ie osteotomy)
7. Patients with an osteochondral injury or chondral injury who require surgical treatment. This is an uncommon but recognised complication of patellar dislocation and is treated surgically in the majority of cases

Date of first enrolment
16/01/2017

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
University Hospital of Coventry and Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Trust
Gobowen
Oswestry
United Kingdom
SY10 7AG

Study participating centre
Morriston Hospital
Abertawe Bro Morgannwg University Health Board
Swansea
United Kingdom
SA6 6NL

Study participating centre
The Bristol Royal Infirmary
Upper Maudlin Street
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Sponsor information

Organisation
University Hospital of Coventry and Warwickshire NHS Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Research organisation

Funder Name
West Midland Clinical Research Network

Results and Publications

Publication and dissemination plan
Planned publication in an orthopaedic or musculoskeletal peer reviewed journal, with a view to a high impact publication from the main trial.

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available as the study is too small to guarantee anonymity of individual participants, but a detailed trial report will be available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		26/05/2020	27/05/2020	No	No
Results article	results	06/07/2020	10/07/2020	Yes	No
HRA research summary			26/07/2023	No	No