

Conservative versus arthroscopic refixation of the Medial PatelloFemoral Ligament (MPFL) after traumatic first time dislocation of the patella in children

Submission date
25/02/2011

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
31/05/2011

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
31/05/2018

Condition category
Injury, Occupational Diseases, Poisoning

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Per-Mats Janarv

Contact details

Department of Pediatric Orthopedics
Astrid Lindgren Children's Hospital
Karolinska University Hospital
Stockholm
Sweden
17176

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Conservative versus Arthroscopic refixation of the Medial Patellofemoral ligament (MPFL) after traumatic first time dislocation of the patella in children: a prospective randomised study

Study objectives

Arthroscopic repair of the MPFL in the acute phase will decrease the redislocation rate compared to conservative treatment with an orthosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The regional Ethics board in Stockholm; D-number: 2008/232-31/4 approved on 5th March 2008 and D-number 2009/1440-32 approved on 17th September 2009

Study design

Prospective single-centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dislocation of patella in children

Interventions

1. The patients will be randomised either to conservative (orthosis) treatment or arthroscopic refixation of the MPFL with the use of anchors
2. The randomisation is made directly after the diagnostic arthroscopy with the patient still under general anesthesia
3. In patients who are randomised to the surgical group, the operation will continue with the arthroscopic repair of the MPFL
4. The aim of this study is to compare the redislocation rate after traumatic first time patellar dislocation between conservative treatment with orthosis for 4 weeks and the new arthroscopic procedure with acute repair of the MPFL injury followed by 4 weeks in plaster
5. All patients will have an MRI and diagnostic arthroscopy within two weeks after the trauma
6. If the arthroscopic findings (MPFL lesion) is the same as the MRI they are randomised on the operating table in the above mentioned two treatment groups
7. The surgical group will continue the arthroscopy with refixation of the MPFL with anchors
8. Both groups will receive physiotherapy until they have regained knee function
9. The follow-up period will be 2 years after arthroscopy

Intervention Type

Mixed

Primary outcome(s)

1. The patients are followed continuously 2 years after arthroscopy at our outpatient clinic
2. If they have any problems with their knee during the study period or redislocation they are advised to contact us for help
3. We will do a physical and radiological examination to confirm the diagnosis and the clinical

findings will be documented in the medical casebook

4. The primary outcome is redislocation rate of the patella compared between the two groups under these 2 years

Key secondary outcome(s)

1. Post-operative complications, knee- examination, joint motion, patient administered scores to evaluate activity, subjective knee function (Lysholm, Tegner score, KOOS-child and Kujala score) and quality of life for children (EQ-5D-Y)

1.1. Kujala score, which is a 13-item questionnaire with discrete categories related to various levels of knee function. Categories within each item are weighted and responses are summarised to provide an overall index in which 100 represents no disability. Among other things, the questionnaire evaluates pain or disability related to the loading of the patellofemoral joint during sitting, walking, running, jumping, and stair climbing. (Kujala et al. Scoring of patellofemoral disorders. *Arthroscopy* 1993;9:159-63). Previous authors have also termed the score 'the Anterior Knee Pain Scale (AKPS)'

1.2. The Lysholm score and Tegner activity scale are commonly used to document outcomes after arthroscopic knee surgery. These outcomes measurements are subjective in nature, and they evaluate performance and activity restrictions both before and after surgery, making them a valuable research tool when judging the effectiveness of surgical treatment. Lysholm score. *Am J Sports Med.* 2003 Jul-Aug; 31(4):487-92. Tegner activity scale from 0-10 *Clin. Orthop. Relat. Res.* 1985 Sep; 198(198):43-9.

1.3. Knee Osteoarthritis Outcome score (KOOS) is developed as an instrument to assess the patients opinion about knee function and associated problems (the child version is on its way to be validated).

1.4. Health and Quality of Life Outcomes 2003, 1:64. The newly developed EQ-5D-Y is a useful tool to measure health related quality of life in young people in an age appropriate manner. *Springerlink.com* ; *Qual Life Res* (2010) 19:875886

1.5. Objective knee function is measured with hop-tests and kneebending/30s-test. Visual analog scales (VAS) are used to assess activity related pains. The outcome will also be correlated to predisposing factors such as Q-angle/TT-TG distance, patella alta, patellar tilt, trochlea dysplasia, and joint mobility according to the Beighton score.

Completion date

30/04/2012

Eligibility

Key inclusion criteria

1. Children 9-14 years of age
2. Admitted to the emergency room (ER) with haemarthrosis after a traumatic first time patellar dislocation
3. The diagnosis is based on clinical examination, magnetic resonance imaging (MRI) and arthroscopy
4. The arthroscopy is the final confirmation of the diagnosis, and it gives a detailed description of the MPFL injury and possible osteochondral lesions
5. Prior to the arthroscopy, the patients are asked to participate in the study
6. The patients who have given informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

9 years

Upper age limit

14 years

Sex

All

Key exclusion criteria

1. Previous significant injury to the same knee including patellar dislocation, systemic joint disease or syndromes affecting the knee joint
2. Osteochondral lesion > 1cm on weight bearing area that needs open reduction and fixation

Date of first enrolment

09/12/2009

Date of final enrolment

30/04/2012

Locations**Countries of recruitment**

Sweden

Study participating centre

Astrid Lindgren Children's Hospital

Stockholm

Sweden

17176

Sponsor information**Organisation**

Capio Research Foundation (Sweden)

ROR

<https://ror.org/04ge4r742>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Department of Pediatric Orthopedics, Karolinska University Hospital (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No