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# 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

**Registration date**
31/05/2011

**Overall study status**
Completed

**Last Edited**
31/05/2018

**Condition category**
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### 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 below to request a patient information sheet

### 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 measure
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

## Secondary outcome measures
1. Post-operative complications, knee- examination, joint motion, patient administrated 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-angel/TT-TG distance, patella alta, patellar tilt, trochlea dysplasia, and joint mobility according to the Beighton score.

## Overall study start date
09/12/2009

### Completion date
30/04/2012

## Eligibility

### Key inclusion criteria
1. Children 9-14 years of age
2. Admitted to the emergency room (ER) with haemartrosis 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 ostechondral 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

### Age group
Child

### Lower age limit
9 Years

### Upper age limit
14 Years

### Sex
Both

### Target number of participants
64 patients

### 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)

**Sponsor details**
Box 8173
Stockholm
Sweden
10420

**Sponsor type**
Research organisation

**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

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**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 |