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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

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Additional identifiers

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

Primary study design
Interventional

Study design
Prospective single-centre randomised controlled trial

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 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.

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

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