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Knee arthroscopy and exercise versus exercise only in relieving pain and disability in patients with chronic patellofemoral pain syndrome (PFPS). A randomized controlled trial.

Submission date
01/11/2005

Recruitment status
No longer recruiting

Registration date
10/01/2006

Overall study status
Completed

Last Edited
03/03/2011

Condition category
Musculoskeletal Diseases

[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Diagnostic and operative arthroscopy in addition to conservative treatment is equally effective as conservative treatment alone for patello-femoral pain syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee approval from the Ethics Committee of the Hospital Districts of Helsinki and Uusimaa, date 30/04/2001.

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic (> 6 months before inclusion) patellofemoral pain syndrome.

Interventions
The aim of this study is to compare the value of diagnostic + operative arthroscopy with home exercise program (arthroscopy group) versus home exercise program only (control group) on subjects with chronic PFPS (patello-femoral pain syndrome). The knee arthroscopy is done one week after the baseline clinical examination by one of the two experienced knee orthopaedists. All knee compartments are examined systematically and pathological findings are recorded. During arthroscopy the following procedures are performed if justified based on the arthroscopy finding and according to our pre-determined quidelines: meniscal resections, resection of inflamed/scarred medial plicae, abrasion of chondral lesions and shaving of excessive and inflamed synovium. Minor corrections of the patellofemoral articulation are performed, such as lateral capsular discision. These cases do remain in the study group. When

necessary, also meniscal refixation, ligament reconstruction and extensive chondral reconstruction are carried out according to current clinical praxis (OATS), even though these patients are not able to participate in standardised training protocol according to the study time-table.

The 8-weeks home exercise program starts 14 days after knee arthroscopy among arthroscopy group and three weeks after the randomization and baseline examination among both groups.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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 summed 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). Many authors who have used this score later have termed it as 'the Anterior Knee Pain Scale (AKPS)'. Main follow-up time-point is 37 weeks after randomization (= 6 months after the exercise training period started three weeks after randomization in both treatment groups). Other time-points when the main outcome is measured are before the randomization, 11 weeks after randomization (immediately after the 8 week home training period = 10 weeks after arthroscopy), 63 week follow-up (= 12 months after the training period), and 115 week follow-up (= 24 months after the training period).

Secondary outcome measures
Three different 10 cm visual analog scales (VASs) to assess activity related pains. Participants assess maximum pain in the previous two days during ascending stairs, descending stairs, and standing up, where 0 = no pain and 100 = extremely intense pain. Also, a global rating of change (overall assessment) is evaluated with an additional 6-point scale: 1 = asymptomatic knee to 6 = marked worsening than before treatment. The subjects also keep a diary related to possible adverse effects and use of drugs as well as on other treatments not related to the study protocol. Adverse effects and a cost-effectiveness analysis will be reported.

Overall study start date
12/02/2003

Completion date
02/02/2005

Eligibility

Key inclusion criteria
In the first phase, orthopaedists select consecutive female or male patients who are admitted to the hospital policlinic of either ORTON Orthopaedic Hospital, Helsinki or one of the orthopaedic policlinics of the Hospital District of Helsinki and Uusimaa and who amongst them fulfil the following inclusion criteria:
1. Subjects that are 18 to 40 years of age female or male and have a characteristic history and

symptoms of PFPS for at least six months
2. They have patellofemoral pain during physical activities, such as jumping, running, squatting, and going up or down stairs; patellofemoral pain when the knee is kept in flexion for a prolonged period, with relief on extension; and possibly, patellar snapping, pseudo-locking, giving-way, stiffness, or periodic effusions in conjunction with physical activity. Subjects with patellar subluxation but not with a history of patellar dislocation, are included.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
56

Key exclusion criteria
1. Subjects with disabling general illnesses, report knee ligamentous or meniscal injuries, previous knee surgery, physician diagnosed knee osteoarthritis or a history of patellar dislocation
2. Subjects who have been in physical therapy for PFPS within the previous 4 weeks
3. Subjects who are pregnant
4. Subjects who are competitive athletes and therefore may have pain syndrome related to extreme loading and perhaps not be willing to follow the treatment protocols
5. Subjects with antero-posterior or medio-lateral instability in manual instability measurement or with knee problems other than PFPS (such as jumper's knee or knee meniscal injury) based on clinical evaluation
6. Subjects with knee osteoarthritis, osteochondritis dissecans, loose bodies in the patellofemoral and tibiofemoral joints, or with knee problems other than PFPS are excluded based on the findings in the knee x-ray examination

Date of first enrolment
12/02/2003

Date of final enrolment
02/02/2005

Locations

Countries of recruitment
Finland

Study participating centre

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Sponsor type
Government

ROR
https://ror.org/057yw0190

Funder(s)

Funder type
Research organisation

Funder Name
Social Insurance Institution of Finland and ORTON Research Institute, Invalid Foundation.

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	13/12/2007		Yes	No
Results article	results	01/03/2012		Yes	No