Rehabilitation after hip arthroscopy for femoroacetabular impingement: comparison of two treatment strategies; usual care physical therapy versus physical therapy aimed at self management.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23095

Source
NTR

Brief title
Not applicable.

Health condition

Femoroacetabular impingement (FAI)
Femoroacetabulair impingement (FAI)
Intra-articular hip pathology
Intra-articulaire heuppathologie
Hip arthroscopy rehabilitation
Postoperatieve revalidatie na heupartroscopie

Sponsors and support

Primary sponsor: Sport Medisch Centrum Papendal
Radboudumc, IQ healthcare

Rijnstate ziekenhuis
Source(s) of monetary or material Support: Fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

- Health-related quality of life measured by the International Hip Outcome Tool 33 (IHOT-33)

- Single Leg Squat Test (SLST)

Secondary outcome

- Tegner activity score

- Hip Sports Activity Scale (HSAS)

- Global Perceived Effect Scale (GPE)

- Range of motion (ROM)

- Hip strength

- Single Leg Hop Test/Star Excursion Balance Test

Study description

Background summary

The amount of hip arthroscopies performed has raised considerably in the last few years. These arthroscopies are often performed for the treatment of Femoroacetabular impingement (FAI). However, it is unclear what postoperative physiotherapeutic rehabilitation should look like. Several postoperative rehabilitation protocols have been described which all include physical therapy treatment and exercises. Therapy goals, frequency and duration of these protocols differ. More important, the studies describing these rehabilitation protocols provide little to no information with regard to clinical outcome data. Only three case studies have described clinical outcome data for postoperative interventions in hip arthroscopy patients. So although the clinician can choose from different rehabilitation protocols, there is little information on the results achieved by following these protocols. This could mean that patients are currently being over- or undertreated. Therefore the goal of this study is to compare two physiotherapeutic rehabilitation strategies; physical therapy (PT) versus self

management. The PT group will visit the physical therapist two times a week and will repeat exercises once a week at home. The self management group visits the physical therapist one time in two weeks and performs the exercises at home three times a week. Both groups will receive the same postoperative rehabilitation with the same exercises, education and hands on physical therapy. Measurements will be performed pre operative, six and 14 weeks post operative with a six months and one-year follow-up. Primary outcomes of this study are perceived hip function and quality of life as measured by the IHOT-33 and actual hip functional performance measured by the SLST.
The results of this study will be used to design a larger randomized controlled trial. Outcomes will be used to calculate the differences in outcome as basis for future power calculation. Moreover, the feasibility and acceptability of both rehabilitation strategies will be evaluated by a short qualitative interview with the participants. Our hypothesis is that the PT group will report a greater improvement in perceived hip function and health-related quality of life as measured with the International Hip Outcome Tool (IHOT-33) and/or hip functional performance as measured with the Single Leg Squat Test (SLST) at 14 weeks post surgery compared to the self management group with a precision of the difference between both groups of 9.4.

Study objective

The aim of this pilot study is to compare two physiotherapeutic rehabilitation strategies in patients who undergo hip arthroscopy for femoroacetabular impingement. Postoperatively, group one will visit the physical therapist two times a week and will repeat the exercises once a week at home (PT-group). The other group visits the physical therapist once in two weeks and performs the exercises at home three times a week (self management group). The results of this study will be used to design a larger randomized controlled trial. Outcomes will be used to calculate the differences between the PF and self-management group with a reasonable precision as basis for future power calculation. Moreover, the feasibility and acceptability of both rehabilitation strategies will be evaluated by a short qualitative interview with the participants.

Our hypothesis is that the PT group will report a greater improvement in perceived hip function and health-related quality of life as measured with the International Hip Outcome Tool (IHOT-33) and hip functional performance as measured with the Single Leg Squat Test (SLST) at 14 weeks post surgery compared to the self management group. We will first test for a difference in IHOT-33 and if present (and only then) for a difference in SLST (hierarchical testing at significance level 0.05).

Study design

The complete rehabilitation with take 14 weeks, excluding the pre operative consult and follow-up measurements. The measurements are conducted at the following time points:

T0 – pre operative (0 weeks)

T1 – 6 weeks post operative

T2 – 14 weeks post operative

T3 – 6 months post operative (26 weeks)

T4 – 1 year post operative (52 weeks)

Intervention

Participants will divided into two groups (PT group versus self management group). The PT group will receive physical therapy treatment two times a week during 14 weeks (24 sessions) whereas the self management group will receive physical therapy treatment approximately once every two weeks (week 2, 4, 6, 8, 10, 12, 14) leading to a total of seven sessions. The PT group will be asked to perform an additional home-based exercise program once a week. The self management group will be asked to perform a similar program three times per week. Subjects in the self management group that report a deterioration on the questionnaires at six weeks post surgery compared to the baseline/pre-oeprative measurement will be excluded from the study and offered regular physical therapy care.

Hip arthroscopy

Spinal needles are placed under image intensifier control to mark the anterior and anterolateral portals. Guide wires and cannulated trocars will be used to introduce cannulae, arthroscopes, and other instruments. A 70° arthroscope will be used to adequately visualize the acetabulum, acetabular labrum, ligaments and the anterior, superior, and posterior aspects of the femoral head. These areas of the hip will be inspected and also probed to assess labral attachment and articular cartilage softening. Pincer-type impingement is typically found in the superior anterior quadrant and will be identified when there is bone overgrowth, a pincer projection causing labral displacement or a crossing sign to be seen over the labrum with fluoroscopy. In order to establish cam-type impingement traction will be released and the peripheral compartment will be investigated. Cam-type impingement will be defined during arthroscopic physical examination, especially during flexion and internal rotation and by the presence of local abnormalities coherent with cam-type impingement, such as chondral lesions. In all cases in which surgically treatable pathology is identified such treatment will be performed arthroscopically.

Immediate postoperative care

Immediate postoperative care will be the same for both groups. Patients will stay in the hospital overnight during one night. They will receive a visit from the physical therapist in the hospital to improve gait function with crutches and get initial advice for the first postoperative week at home. A follow-up visit to the orthopedic surgeon will be scheduled 6

weeks after surgery.

Physical therapy

Physical therapy treatment will start two weeks post surgery for both groups. For the first two postoperative weeks both groups will start self mobilizations and basic stability exercises unsupervised on a daily basis at home.
Both groups will receive the same postoperative physiotherapeutic rehabilitation with the same hands on physical therapy, exercises and education. Group 1 (PT) will receive hands on physical therapy care and conduct exercises supervised by a physical therapist twice a week and unsupervised (at home) once a week. Group 2 (self management) will conduct these exercises three times a week at home with supervision and treatment by a physical therapist once every two weeks. The exercises consist of strength and stability exercises as well as self mobilizations of the hip, pelvis and lumbar spine. Education will consist of information on joint protection and regaining complete function in activities of daily living and work. Hands on physiotherapeutic care consists of manual mobilizations, massages and triggerpoint therapy by a physical therapist. Group 1 will be able to receive this care twice a week. Group 2 will receive this physiotherapeutic care once every two weeks.

Contacts

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Eligibility criteria

Inclusion criteria

- Between 18 and 50 years of age

- Hip/groin pain for at least three months

- Diagnosed with FAI by orthopedic surgeon based on symptoms, clinical signs and imaging findings

- Scheduled for hip arthroscopy

- Willing to sign informed consent

Exclusion criteria

- Radiographic evidence of hip osteoarthritis (> Tonnis grade 1)

- Contra-indications for the hip arthroscopy procedure

- Other pathologies, such as cardiovascular disease, that can influence therapy effects

- Inability to speak or understand the Dutch language

- Inability to comply with postoperative rehabilitation and exercises due to other reasons, such as a lack of time etcetera.

- Professional athletes

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2015
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-05-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5022
NTR-old	NTR5168
Other	CMO Arnhem-Nijmegen : 2015-1730

Study results

Summary results
Intention of publication of study protocol before completion of patient inclusion (at least within one year time after start of patient inclusion) and of study results after the study is finished.