Hip Arthroscopy Study

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The standardized hip arthroscopy procedure is a safe method to significantly improve both functional outcome and quality of life in patients with femoroacetabular impingement or acetabulum labrum tears or damage.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27033

Bron
Nationaal Trial Register

Verkorte titel
Hip Arthroscopy Study

Aandoening

Hip arthroscopy, femoroacetabular impingement, acetabulum labrum tears

Ondersteuning

Primaire sponsor: Reinier de Graaf Groep, afdeling orthopedie
Overige ondersteuning: Reinier de Graaf Gasthuis, Delft

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main parameters are:
- Functional outcome; measured by the modified Harris Hip Score
- Improvement of pain; measured by the EQ-5D

- Complications rate; recorded in minor and major complications

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Arthroscopy of the hip is a well-recognized intervention, expanding indications for hip surgery. Main indications for arthroscopy are the femoroacetabular impingement (FAI) syndrome and tears or damage of the acetabular labrum. Due to improved visual diagnostic tools, indications for hip arthroscopic interventions are more accurate. Despite this, there is still a lack of large cohorts with long-term follow up and the amount of studies describing short-term follow up after interventions is sparse. The complication rate of arthroscopy is still reported as very low, though re-intervention arthroscopy can be required. Femoroacetabular impingement is a diagnosis much described in middle-aged patients. Much profit could therefore be achieved by successful surgery in terms of functional outcomes and quality of life. Also, femoroacetabular impingement is described to contribute to the develoment of osteoarthritis. Therefore, hip arthroscopy is a very promising technique, which could delay or even prevent the occurrence of osteoarthritis. To improve techniques and to describe its success rate, long term follow up with monitoring of patients is required.

Objective:

The main objective is to measure the functional outcome and recovery of patients after hip arthroscopy, using clinician and patient based outcome scores (modified Harris Hip Score, Hip Outcome Score, iHOT12-NL and visual analogue scale). In addition, we will measure the improvement in quality of life with the EuroQoL-5D. Complications will be registered.

Study design:

A prospective patient controlled multi-center study with clinician and patient based questionnaires

Study population:

Patients are selected from the orthopedic outpatients’ clinics. Patients aged 15-65 years without previous arthroscopic hip surgery or metastatic malignancies who have suspected

FAI or labral tears are included in this study. FAI or labral tears are either diagnosed clinically, by MRI or by marcainization.

Main study parameters/endpoints:

The main study parameters will be the long-term functional outcome and quality of life after interventional hip arthroscopy for femoroacetabular impingement or acetabular labrum tears or damage, measured with patient and clinician based score systems. Our hypothesis is that hip arthroscopy is a method to significantly improve functional outcome and quality of life in patients with femoroacetabular impingement or acetabulum tears or damage with minimal re-interventions and very low complication rate.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
all patients will receive their planned hip arthroscopy. There will be no extra control visits compared to normal patient care. All study patients are asked to fill in questionnaires during follow up moment in the outpatients' clinic, or to fill in the questionnaire at home and return it by mail.

Doel van het onderzoek

The standardized hip arthroscopy procedure is a safe method to significantly improve both functional outcome and quality of life in patients with femoroacetabular impingement or acetabulum labrum tears or damage.

Onderzoeksopzet

- preoperative

- 6 weeks post-operatively

- 3 months post-operatively

- 1 year post-operatively

- 2 years post-operatively

- 5 years post-operatively

- 10 years post-operatively

Onderzoeksproduct en/of interventie

Patients undergo routine physical examination before surgery and at 3 months and 12 months after surgery. They will also complete questionnaires (consisting of Hip Outcome Survey, iHOT12-NL, VAS, EQ-5D and 4DKL preoperatively, and of Hip Outcome Survey, iHOT12-NL, VAS, EQ-5D and an achorquestion postoperatively).

Every patient receives a hip arthoscopy, as neede for the type of his or her injury. The study design does not interfere with the surgery protocol.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients who:

- Are 15-65 years of age.

- Have a physical examination, which is suspect for femoroacetabular impingment, or an acetabulum labrum tear or lesion, or are suspect to loose bodies in the hip joint, chondral lesions or osteophytes impingement.

- Have no contraindications for MRI.

- Are willing to return for regular evaluation visits.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients who:

- Are <15 or >65 years of age.

- Have had prior surgery for femoroacetabular impingement.

- Complaints caused by other diagnoses than the ones in inclusion criteria.

- Have pathological fractures or other metastatic pathology as a cause of the hip/groin pain.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2015
Aantal proefpersonen:	0
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6610
NTR-old	NTR6792
Ander register	METC Zuidwest Holland : 16-080

Resultaten