Gait analysis after THA

Gepubliceerd: 13-04-2017 Laatst bijgewerkt: 18-08-2022

Different gait analysis tests can be used for the anterior and posterolateral approach in THA.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25459

Bron
NTR

Verkorte titel
Gait analysis, direct anterior approach, total hip arthroplasty, posterolateral approach

Aandoening

Osteoarthritis

Ondersteuning

Primaire sponsor: Martini Hospital Groningen
Overige ondersteuning: Martini Hospital Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to conduct a prospective pilot study to assess the optimal measurements of gait function following THA via both the anterior and the posterolateral approach. This will be measured with three different methods:
- Ground reaction forces will be measured during the stance phase of gait with force plates;
- Three dimensional (3D) motion analysis will assess the movement of the patients’

body;
- muscle activity during gait will be measured with EMG.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Total hip arthroplasty (THA) remains one of the most successful orthopaedic interventions of the last decades, with 10-year survival now exceeding 95%. Because of the ageing and the increasing obesity in Western societies, it is expected that the number of THAs will only rise in the future. Driven by this growing demand for THA, together with a greater emphasis on cost-effectiveness in health care and patients' higher expectations of shorter hospital stays and faster recovery, alternative surgical procedures have been developed to improve the success of THA. The anterior approach for THA is one of these developments. Compared to conventional approaches for THA, such as the posterolateral approach, the anterior approach for THA is considered to result in less damage to soft tissues, such as muscles and tendons, during surgery in order to enhance postoperative recovery and, consequently, in an accelerated return to normal daily functioning. To assess whether the proposed increase in muscle damage is of any clinical influence, gait analysis can be performed. Gait analysis is the most reliable way to measure patients' function postoperatively. Furthermore, muscle activity measurements can be used to identify any existing differences. However, there is a lack of evidence on the best way to assess muscle damage after THA.

Objective: To conduct a pilot study to determine the best way to analyse gait and muscle function following anterior and posterolateral approach for THA.

Study design: A prospective non-randomized pilot study will be performed. The patients will be allocated to undergo THA by either the anterior of the posterolateral approach. The choice for approach will be made by the treating orthopaedic surgeon in close dialogue with the patient.

Study population: Patients who are admitted for primary unilateral THA will be included in the pilot study. Both the intervention and control groups will consist of two subgroups: patients with a good bone stock who will receive an uncemented femoral stem and a subgroup of patients who will receive a cemented femoral stem. In total, 12 patients will be included in the study.

Intervention: Patients in the study group will undergo THA using the minimally invasive single-incision anterior approach. This approach will be compared to the conventional

posterolateral approach.

Main study parameters/endpoints: Measurements will take place preoperatively and 6 weeks postoperative. The main study parameter will be the ground reaction force (GRF) during the stance phase of the patients' gait. These forces give indirect information about the load in the hip joint during gait. Additionally, motion analysis measurements will be performed to assess the movement of the body during gait. Finally, electromyography (EMG) measurements will be performed to measure muscle activity during gait.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Since both the anterior and posterolateral approach for THA are standard approaches for THA, no additional risks are associated with participation of the study. With gait function, walking pattern of the patients is assessed. Patients do not have to perform motor tasks which they are not used to perform.

Furthermore, no invasive procedures are performed during motion analysis and EMG measurements. So no risks are involved with the gait function measurements.

Doel van het onderzoek

Different gait analysis tests can be used for the anterior and posterolateral approach in THA.

Onderzoeksopzet

Preoperative and six weeks postoperative

Onderzoeksproduct en/of interventie

Patients in the anterior approach group will undergo THA using the minimally invasive single-incision anterior approach. An anterior incision centred over the hip joint is made in a supine patient. After division of skin and subcutis, the interval between the m. tensor fasciae latae and the m. sartorius is identified and the overlying fascia is opened. In this part of the operation care must be taken to avoid damaging the n. cutaneous femoris lateralis, supplying the skin on the lateral part of the thigh. The intermuscular plane between the m. tensor fasciae lata and the m. sartorius is developed further down to the hip capsule. Subsequently the hip capsule is opened, allowing access to the hip joint. Preparation of the hip for implantation of a hip prosthesis can take place now, by in situ performance of the collum osteotomy, removal of the femoral head and reaming of the acetabulum. Next, bone cement (Palacos®, Heraeus Medical, The Netherlands) is pressurized into the acetabular cavity, followed by insertion of the acetabular cup. After reaming of the femur, the femoral component can be placed with or without bone cement, followed by placement of a head on the femoral component, repositioning of the joint and closure in layers. In case of a cemented femoral component, bone cement is pressurized into the femoral cavity before the femoral component of the hip prosthesis is placed.

The other group patients will undergo the posterolateral approach, in which the patient is placed in a lateral position. After transection of the subcutis, the fascia latae and glutae are split. Next, the short external rotators are cut at the level of their insertion at the greater trochanter, so this approach is not muscle-sparing. In this phase of the procedure, caution is advised with the sciatic nerve, the main nerve for the lower leg. After retraction of the short external rotators backwards, the hip capsule becomes visible and can be incised, allowing access to the hip joint. The rest of the operation will essentially take place in the same manner as the anterior approach.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age between 18 – 90 years;

- Indication for THA is primary or secondary symptomatic osteoarthritis

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- A history of previous surgery on the ipsilateral hip;

- symptomatic osteoarthritis of the contralateral hip;

- a hip prosthesis at the contralateral side two years prior to current trial;

- symptomatic osteoarthritis of the knee;

- peripheral neuropathy;

- (active) arthritis (e.g. rheumatic disease);

- a history of CVA;

- COPD GOLD III or IV

- NYHA class III or IV

- cognitive impairments.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2017

Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-04-2017
Soort:	Eerste indiening

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	NL5994
NTR-old	NTR6393
Ander register	Regionale Toetsingscommissie Patiëntgebonden Onderzoek, Leeuwarden : RTPO 999

Resultaten