

A (cost-) effectiveness of the anterior approach compared to the posterolateral approach for total hip arthroplasty

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The anterior approach will result in a faster postoperative recovery and will be more (cost-) effective

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26182

Bron

NTR

Verkorte titel

Direcht anterior approach, posterolateral approach, THA, gait analysis, total hip arthroplasty

Aandoening

Primary or secondary osteoarthritis of the hip

Ondersteuning

Primaire sponsor: Martini Hospital, Department of Orthopaedic Surgery

Overige ondersteuning: Martini Hospital, Department of Orthopaedic Surgery

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary aim of this study is to assess the clinical effectiveness of the anterior approach

compared to the conventional posterolateral approach, in terms of physical functioning and health-related quality of life.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Total hip arthroplasty (THA) is considered to be one of the most successful orthopaedic interventions of the past 40 years, with 10-year survival rates exceeding 90%. The number of THAs has increased rapidly during the last decade, because of ageing of Western societies and an increase of the incidence of obesity. 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. It is expected that elderly patients (aged 70 years and over) may benefit even more from the anterior approach, because of their decreased regenerative capacity to recover from tissue damage. However, there is a lack of well-designed studies, and thus of objective evidence, on the (cost)effectiveness of the anterior approach, with special attention to its effect on elderly THA patients.

Objective:

To assess the clinical and cost effectiveness of the anterior approach, compared to the conventional posterolateral approach for THA in terms of physical functioning and health-related quality of life.

Study design:

A randomized controlled trial. Patients will be randomly allocated to undergo THA by means of the anterior approach or the posterolateral approach.

Study population:

Patients who are admitted for primary unilateral THA will be included in the study. Both the intervention and control groups will consist of two subgroups: patients with an age of ≤ 70

years, provided that they have a good bone stock, and a subgroup with patients aged >70 years. In total, 260 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. In both study groups, the same hip prosthesis will be used. An uncemented femoral component will be placed in patients with a good bonestock and a cemented femoral component will be placed in patients who have a poor bone stock. In both groups, a cemented acetabular component will be placed.

Main study parameters/endpoints:

Measurements will be made preoperatively, and two and six weeks, and three months and one year postoperatively. Main study parameter is the Patient Acceptable Symptom State (PASS) which will be derived from the Hip disabilities and Osteoarthritis Outcome Score (HOOS). Preoperative demographic data, preoperative diagnosis, height, weight and BMI, ASA classification and the Kellgren-Lawrence scale will be recorded. Several parameters of surgical outcome will be recorded. Physical functioning and health-related quality of life will be determined subjectively by means of questionnaires. Additionally, physical functioning will be assessed objectively by means of gait function measurements (Timed Up and Go test, and the 4x10m self-paced walk test and the stair-climb test). These measurements will take place at the above stated time points and at two weeks postoperatively. Participation will also be assessed by means of questionnaires. Cost-effectiveness will be assessed by means of obtaining data on medical costs in and outside the hospital, and other nonmedical costs.

Doel van het onderzoek

The anterior approach will result in a faster postoperative recovery and will be more (cost-) effective

Onderzoeksopzet

Measurements will take place preoperatively, 2 and 6 weeks, 3 months and 1 year postoperatively

Onderzoeksproduct en/of interventie

Patients in the study 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 anterior approach will be compared to the conventional posterolateral approach, in which the patient is placed in a lateral position. After transection of the subcutis, the fascia latae and gluteae 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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Wetenschappelijk

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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;v
complaints of the contralateral hip;

a hip prosthesis at the contralateral side;

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;

not able to fill in questionnaires in the Dutch language.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2015
Aantal proefpersonen:	260
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	NL5195
NTR-old	NTR5343

Register **ID**

Ander register Regionale Toetsingscommissie Patiëntgebonden Onderzoek, Leeuwarden :
RTPO 939

Resultaten