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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26182

Source
NTR

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

Health condition

Primary or secondary osteoarthritis of the hip

Sponsors and support

Primary sponsor: Martini Hospital, Department of Orthopaedic Surgery
Source(s) of monetary or material Support: Martini Hospital, Department of Orthopaedic Surgery

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To determine the effectiveness of the anterior approach on surgical outcome;

To determine the effectiveness of the anterior approach on gait function;

To determine the effectiveness of the anterior approach on social and work participation;

To determine the cost-effectiveness of the anterior approach.

Study description

Background summary

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 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.

Study objective

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

Study design

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

Intervention

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 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.

Contacts

Public
Department of Orthopaedics - Martini Hospital

K. (Kyrill) Rykov
P.O. Box 30033

Groningen 9700 RM
The Netherlands
Phone: 050 524 59 70
Scientific
Department of Orthopaedics - Martini Hospital

K. (Kyrill) Rykov
P.O. Box 30033

Groningen 9700 RM
The Netherlands
Phone: 050 524 59 70

Eligibility criteria

Inclusion criteria

Age between 18 – 90 years;

Indication for THA is primary or secondary symptomatic osteoarthritis.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2015
Enrollment:	260
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL5195
NTR-old	NTR5343
Other	Regionale Toetsingscommissie Patiëntgebonden Onderzoek, Leeuwarden : RTPO 939

Study results