The anterior vs the posterolateral approach for THA: is there a difference in tissue damage?

No registrations found.

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

Summary

ID

NL-OMON24737

Source
NTR

Health condition

total hip arthroplasty (THA)

Sponsors and support

Primary sponsor: Dept. of Orthopaedics
Martini Hospital Groningen
Source(s) of monetary or material Support: NOREF Annafonds

Intervention

Outcome measures

Primary outcome

Tissue damage will be assessed via the enumeration of the tissue macrophages in blood (over time), preferably also using specific antibodies against fragments of tissue-specific proteins, such as soft tissue and skeletal muscle. Multiparameter (≥ 8 colors) flow cytometry can accurately detect and identify the circulating tissue macrophages with a first set of antibodies against membrane markers. The absolute and relative numbers of the blood tissue

macrophages during and after the THA procedure should be able to give insight into the extent of tissue damage in individual patients. In addition, the levels of serum creatine kinase (CK), creatine phosphokinase (CPK), and C-reactive protein (CRP) will be assessed.

Secondary outcome

Besides a relative and quantitative assessment, the secondary study parameter will be the presence of bone- and muscle- specific protein fragments in the circulating macrophages. The presence of these fragments, might be related to the extent of bone and muscle damage, potentially allowing a more accurate assessment of damage caused by the different THA approaches.

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. Tissue damage can be assessed by means of biochemical blood markers such as serum creatine kinase (CK), creatine phosphokinase (CPK), and C-reactive protein (CRP). It is also known that macrophages are key regulators of tissue repair and regeneration. Macrophage activity is therefore another useful blood marker for the amount of tissue damage.

Objective:

To conduct a randomised controlled trial to determine differences in the level of blood markers for tissue damage following the anterior approach and posterolateral approach for THA.

Study design:

A randomised controlled trial will be executed. Patients will be randomly allocated to undergo THA by means of the anterior approach or the posterolateral approach. The trial will be conducted at the department of Orthopaedics of the Martini Hospital Groningen.

Study population:

Patients who are admitted for primary unilateral THA will be included in the study. Intervention (if applicable): 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 for THA.

Main study parameters/endpoints:

Tissue damage will be assessed via the enumeration of the tissue macrophages in blood (over time). The absolute and relative numbers of the blood tissue macrophages during and after the THA procedure should be able to give insight into the extent of tissue damage in individual patients. In addition, the levels of serum creatine kinase (CK), creatine phosphokinase (CPK), and C-reactive protein (CRP) will be assessed.

Study objective

The aim of this study is to determine differences in the level of blood markers for tissue damage following the anterior approach and posterolateral approach for THA.

Study design

Blood samples are taken on the following time-points:

1. Preoperatively (day of admission);

2. Immediately postoperative (2-3 hours);

3. Postoperative days 2;

4. Postoperative day 3;

5. Postoperative day 4;

6. 6 weeks postoperatively.

Additionally, one extra blood sample will be collected immediate postoperatively (2-3 hours).

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 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.

Patients in the control group will undergo the posterolateral approach, during 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
Martini Hospital Groningen
Dept. of Orthopaedics
P.O. Box 30033
I.H.F. Reininga
Groningen 9700 RM
The Netherlands
Scientific
Martini Hospital Groningen
Dept. of Orthopaedics
P.O. Box 30033
I.H.F. Reininga
Groningen 9700 RM

The Netherlands

Eligibility criteria

Inclusion criteria

1. Age between 18 and 90 years;

2. Indication for THA is primary or secondary symptomatic osteoarthritis.

Exclusion criteria

1. A history of previous surgery on the ipsilateral hip;

2. Peripheral neuropathy;

3. (Active) arthritis (e.g. rheumatic disease);

4. A history of CVA;

5. Cognitive impairments.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2013

Enrollment:	46
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	NL3768
NTR-old	NTR3926
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A