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

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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.

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

Samenvatting

ID

NL-OMON24737

Bron
NTR

Aandoening

total hip arthroplasty (THA)

Ondersteuning

Primaire sponsor: Dept. of Orthopaedics
Martini Hospital Groningen
Overige ondersteuning: NOREF Annafonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

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. 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

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 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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 18 and 90 years;

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2013

Aantal proefpersonen:	46
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	NL3768
NTR-old	NTR3926
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A