Computer-assisted Minimally Invasive Total Hip Surgery (MIS): a randomized controlled trial into the effectiveness compared to traditional Total Hip Arthroplasty.

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It is our hypothesis that MIS will lead to better recovery compared to traditional total hip surgery during the early postoperative period (3 months), and at least as good at 6 months postoperatively.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24337

Bron
NTR

Verkorte titel
MIS-study

Aandoening

Computer-assisted minimally invasive total hip surgery versus traditional total hip surgery.

Ondersteuning

Primaire sponsor: Department of Orthopaedic Surgery, University Medical Center Groningen (UMCG)
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Does computer-assisted MIS lead to a better recovery during the early postoperative period (3 months), and at 6 months postoperatively to a recovery at least as good as THA with a traditional incision technique? In this study, recovery is operationalised as the the proportion of subjects with normal gait (no limping during walking) as objectified by gait analysis, and as the self-reported functional status and health-related quality of life.

Toelichting onderzoek

Achtergrond van het onderzoek

Moderate to severe osteoarthrosis is the most common indication for Total Hip Arthroplasty (THA). THA has proven to be one of the most successful orthopedic interventions. Minimally Invasive Total Hip Surgery (MIS) and Computer Assisted Surgery (CAS) were introduced several years ago. However, the literature lacks well-designed studies that provide objective evidence of the superiority of computer-assisted MIS compared to a traditional technique. For that reason, the purpose of this study is to compare the effectiveness of computer-assisted MIS with a traditional technique for THA. Primary research question is if computer-assisted MIS leads to a better recovery during the early postoperative period (3 months), and at 6 months postoperatively to a recovery at least as good as THA with a traditional incision technique. Additionally, does it lead to a decrease in length of hospital stay, fewer perioperative complications and a better positioning of the prosthesis, and are there indications for potential cost savings.
A cluster randomized controlled trial will be executed. Patients will be stratified by means of the Charnley classification. They will be randomly allocated to have MIS using the minimally invasive single-incision anterior approach or the traditional procedure using a standard posterolateral incision. Measurements take place preoperatively, perioperatively, and 6 weeks and 3 and 6 months postoperatively. In this study the primary focus will be on the 6-week and 3-month results. For the 6-month results, analyses will be done with the data available within the two-year period, after which the follow-up of patients will be completed, making it possible to answer the research questions at 6 months too. Patients with a maximum of 75 years of age admitted for primary cementless unilateral THA will be included. Preoperative and postoperative functional status will be recorded objectively by means of gait analysis. As walking is by far the most important aspect of functional status, we will focus on it, especially on the extent of limping during walking, as this is an evident indication of return to a normal gait. To qualify prosthesis positioning, a radiographic evaluation will take place. Self-reported questionnaires will be used to get an impression of self-reported functional status (WOMAC, SF-36 and EuroQol).

At 3 months, the effect of MIS and traditional THA on gait will be compared using chi-square procedures. To be able to detect a difference of 0.254 in the proportion of subjects with normal gait after 3 months of follow-up with 80% power at a significance level of 0.05 in a one-sided test of a difference between two proportions, two groups of 50 subjects are required. At 6 months the effect of MIS and traditional THA on gait (limping) will be compared in a non-inferiority setting. The non-inferiority margin delta is chosen in this study at a value of 0.10, indicating that a difference in proportion of subjects with normal gait of 0.10 is considered clinically equivalent. To deduce non-inferiority with 80% power at a significance level of 0.05 with expected proportions of subjects with normal gait of 0.95 using a non-inferiority margin delta of 0.10, two groups of 60 subjects are required. Descriptive statistics will be used to describe both research groups. Analysis of variance (ANOVA) and chi-square procedures will be used to evaluate between-group differences at baseline.
Economic evaluation will focus on differences in costs between computer-assisted MIS and standard THA. The evaluation will be performed from a societal perspective, costs within and outside the healthcare sector will be registered for 6 months. Cost advantages of MIS over THA are expected mainly in the area of hospitalization costs. Additional economic analyses will estimate the cost effectiveness of MIS compared to THA.

Doel van het onderzoek

It is our hypothesis that MIS will lead to better recovery compared to traditional total hip surgery during the early postoperative period (3 months), and at least as good at 6 months postoperatively.

Onderzoeksproduct en/of interventie

Treatment of intervention group

Patients in the MIS group will have surgery using the minimally invasive single-incision anterior approach (Rachbauer et al., 2004). The anterior approach is one of the several possible approaches to the hip joint. Using special retractors, reamers and insertion handles it is possible to perform this procedure in a minimally invasive way, limiting the skin incision from about 15 cm to about 8 cm. Advantage of the anterior approach is the possibility of using intermuscular planes, avoiding muscle damage by cutting or detaching muscles and adding to the minimally invasive character of the 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 lata 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, followed by insertion of an uncemented acetabular cup. After reaming of the femur an uncemented femoral component can be placed, followed by placement of a head on the femoral component, repositioning of the joint and closure in layers. To optimize

placement of the acetabular and femoral components of the total hip prosthesis, computer navigation will be used. In order to use computer navigation it is necessary to place two trackers on the patient, which are used by the computer for referencing. These trackers are temporarily fixed on the patient by a small anchoring pin in the pelvis (spina iliaca anterior superior) and in the distal femur.

Treatment of control group

The minimally invasive technique will be compared to the traditional posterolateral approach, in which the patient is placed in a lateral position. After transsection of the subcutis, the facia 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 minimally invasive surgical technique.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with a minimum age of 18 years and a maximum of 75 years of age who are admitted for primary cementless unilateral THA, due to primary or secondary osteoarthrosis, will be included. Prior to providing informed consent, patients will be made aware that they will be blinded to the size of the incision for the duration of the hospital stay.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with inflammatory polyarthritis or with a history of previous surgery on the affected hip will be excluded. Additionally patients with dementia and patients who are not able to fill in questionnaires in the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2007
Aantal proefpersonen:	132
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2006

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	NL738
NTR-old	NTR748
Ander register	:
ISRCTN	ISRCTN52538512

Resultaten

Samenvatting resultaten
Not available