Total hip arthroplasty: Anterior supine intermuscular versus transgluteal approach, a prospective study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26281

Source
Nationaal Trial Register

Brief title
ASI study

Health condition

total hip arthroplasty, anterior supine intermuscular

Sponsors and support

Primary sponsor: Spaarneziekenhuis Hoofddorp en tevens het Stimulerinsfonds van het Linneusinstituut
Source(s) of monetary or material Support: Stimuleringsfonds van het Linneusinstituut

Intervention

Outcome measures

Primary outcome

Function: Harris Hip Score.

Secondary outcome

Pain, complications, length of incision, blood loss, range of motion, length of hospital stay, complications, radiograph.

Study description

Background summary

Background:

We present the design of a open randomised controlled study of anterior supine intermuscular (ASI) versus transgluteal approach of total hip arthroplasty (THA). The study is designed to evaluate functional outcome after both approaches.

Methods/Design:

in this randomized controlled trial, 120 consecutive primary noncemented THAs in 120 patients were assigned to one of two groups (ASI or transgluteal). The primary outcome was functional outcome (Harris hip score) at six weeks and one year postoperatively.

Conclusion:

By making this design study we wish to contribute to more profound research on the anterior approach of total hip arthroplasty.

Study objective

The hypothesis of this study is patients with a primary total hip arthroplasties through the anterior supine intermuscular approach will show faster improvement in in walking ablility and mobilization in the postoperative period in comparison with those managed with the transgluteal approach.

Study design

2 days, 6 weeks, 3 months, 6 months, 1 year.

Intervention

Total hip arthroplasty through anterior supine intermuscular and transgluteal approach.

Anterior supine intermuscular approach:

Supine position of the patient on the operating table with the possibility of hyperextension in the mid-table in order to facilitate femoral exposure. Anterior incision, 6-9 cm long, starting approximately 2cm lateral and 5 cm distal of the anterior iliac spine. Incision of the fascia, blunt preparation in the intermuscular space between tensor fascia latae muscle and sartorius muscle. Exision of the anterior parts of the capsule. Osteotomy of the femur by hyperextension, adduction and externeal rotation of the leg, incision of the posterior capsule for easy anteriorrization of the femur. Reaming and implantation of the acetabular component. next , the femur was externally rotated and the capsule carefully detached from the greater trochanter. the entrance into the meddulary canal was lifted to achieve unimpaired access for the offset of broaches. a special two-prolonged retractor was inserted between the tendons of the gluteus medius and minimus and the greater trochanter to provide additional leverage. the adducted femur was broached for a cementless stem. since no muscles were split, the fascia between the
Sartorius muscle and tensor muscle was sutered. The subcutaneous fat and skin were sutured.

Surgical technique transgluteal approach:

Supine position of the patient on the operating table. A straight lateral incision is made over the greater trochanter. The iliotibial tract is exposed and divided longitudinally just posterior to the insertion of the tensor fascia lata. The ventral third of vastus lateralis muscle and the gluteal muscle was detached from the bone in one coherent layer using diathermy. The exposed capsule was then opened, and the femoral head was dislocated. Following osteotomy of the femoral neck, the cup was reamed for a cementless cup. For the preparation of the femoral canal, the operated limb was adducted below the contralateral one and rotated outward. The external rotators near the intertrochanteric fossa were tenotomised. While holding back the gluteal muscles, the femur was broached for an uncemented stem. After implantation, the gluteus medius and vastus lateralis was adapted. Then, de fascia latea was closed. The subcutaneous fat and skin were sutured.

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Eligibility criteria

Inclusion criteria

1. Indication THA;

2. Primairy arthrosis;

3. BMI<30 kg/m;

4. General anesthesia;

5. <80 jaar;

6. ASA-classification I en II.

Exclusion criteria

1. Previous surgery of the hip before;

2. Fractures;

3. Inflammatory polyarthritis;

4. Local anesthesia;

5. CVA/TIA or MI last half year;

6. ≥ 80 year;

7. ASA-classification III and IV.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-07-2012
Application type:	First submission

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	NL3373
NTR-old	NTR3520
Other	METC / CCMO : M010-072 / NL3394609410;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A