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Computer-assisted Minimally Invasive total hip Surgery (MIS): a randomised controlled trial into the effectiveness compared to traditional total hip arthroplasty

Submission date
22/11/2006

Recruitment status
No longer recruiting

Registration date
22/11/2006

Overall study status
Completed

Last Edited
06/01/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL738, NTR748

Study information

Scientific Title
Computer-assisted Minimally Invasive total hip Surgery (MIS): a randomised controlled trial into the effectiveness compared to traditional total hip arthroplasty

Acronym
MIS-study

Study objectives
It is our hypothesis that Minimally Invasive total hip Surgery (MIS) will lead to better recovery compared to traditional total hip surgery during the early postoperative period (three months), and at least as good at six months postoperatively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hip diseases

Interventions
Treatment of intervention group:
Patients in the MIS group will have surgery using the minimally invasive single-incision anterior approach. 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.

The advantage of the anterior approach is the possibility of using inter-muscular 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 optimise 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 trans-section 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.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Does computer-assisted MIS lead to a better recovery during the early postoperative period (three months), and at six months postoperatively to a recovery at least as good as THA with a traditional incision technique?

In this study, recovery is operationalised as 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.

Key secondary outcome(s))
1. Does computer-assisted MIS result in a decreased length of hospital stay compared to THA with a traditional incision technique?
2. Does computer-assisted MIS lead to the same or even better positioning of the prosthesis compared to THA with a traditional incision technique as measured by means of radiographic evaluation?
3. Does computer-assisted MIS lead to a decrease in perioperative complications compared to THA with a traditional incision technique?
4. Are there indications that computer-assisted MIS potentially saves costs compared to a traditional incision technique?

Completion date
01/01/2010

Eligibility

Key inclusion criteria
1. Minimum age of 18 years and maximum of 75 years of age
2. Admitted for primary cement-less unilateral Total Hip Arthroplasty (THA), due to primary or secondary osteoarthrosis

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.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Total final enrolment
75

Key exclusion criteria
1. Inflammatory polyarthritis
2. A history of previous surgery on the affected hip
3. Dementia
4. Not able to fill in questionnaires in the Dutch language

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
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Sponsor information

Organisation
University Medical Center Groningen (UMCG) (The Netherlands)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organization for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2013	06/01/2021	Yes	No
Protocol article	protocol	11/01/2007	06/01/2021	Yes	No