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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON29885

Source
ToetsingOnline

Brief title
MIS-study

Condition

- Joint disorders

Synonym
osteoarthrosis, total hip arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZONmw

Intervention

Keyword: Computer Assisted Surgery, Minimal Invasive Surgery, Total Hip Arthroplasty

Outcome measures

Primary outcome

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 operationalized as the amount of limping during walking as objectified by gait analysis, and as the self-reported functional status and health-related quality of life.

Secondary outcome

Does computer-assisted MIS result in a decreased length of hospital stay compared to THA with a traditional incision technique?

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?

Does computer-assisted MIS lead to a decrease in perioperative complications compared to THA with a standard incision technique?

Are there indications that computer-assisted MIS potentially saves costs

compared to a traditional incision technique?

Study description

Background summary

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.

Study objective

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.

Study design

A cluster randomized controlled trial will be executed. Patients (N=132) 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.

Intervention

Patients in the MIS group will have surgery using the minimally invasive single-incision anterior approach. 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. To optimize placement of the acetabular and femoral components of the total hip prosthesis, computer navigation will be used. The minimally invasive technique will be compared to the traditional posterolateral approach. The anesthetic,

analgesic and postoperative physiotherapy protocols will be standardized.

Study burden and risks

There are no additional risks with respect to participation in this study other than the normal risks if a regular procedure would have been executed.

The extent of the burden for participating patients is limited. They have to fill in a questionnaire 4 times and execute a gait analysis 4 times (approximately 30 min in total each time). These measurements will take place in combination with the regular pre- end postoperative visits to the outpatient clinic. Only for the thrid measurment patients have to come back to the outpatient clinic seperately.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Primary or secondary osteoarthrosis
A minimum age of 18 years
A maximum age of 75 years
Admitted for a cementless total hip arthroplasty

Exclusion criteria

Inflammatory polyarthritis
Previous surgery on the affected hip
Dementia
Not able to fill in questionnaires in the Dutch language

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2007
Enrollment:	132
Type:	Actual

Ethics review

Approved WMO

Date:	04-10-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL13556.042.06
Other	nog niet bekend