Comparison Of Posterolateral and direct Anterior approach in uncemented total hip arthroplasty: treatment outcome and cost-effectiveness

Published: 30-01-2015
Last updated: 20-04-2024

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

Summary

ID

NL-OMON55723

Source
ToetsingOnline

Brief title
COPA study

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
degeneration, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep
Source(s) of monetary or material Support: Stichting ALK-resort

Intervention

Keyword: elderly, hip replacement, mobility

Outcome measures

Primary outcome

Functional outcome parameters

Disability, functioning during daily living, recreational activities and sports (Hip dysfunction and Osteoarthritis Outcome Score) will be assessed preoperatively and at 6 weeks, 3 months, 6 months, 12 months, and 24 months after surgery.

Secondary outcome

Clinical outcome parameters

Perceived pain is assessed preoperatively and during the first 3 days after surgery (VAS pain). Length of hospital stay is registered. Quality of Life (EQ-5D), perceived pain and symptoms, and complications are assessed preoperatively and at 6 weeks, 3 months, 6 months, 12 months, and 24 months after surgery.

Functional outcome parameters

Quality of walking will be assessed preoperatively and at 1 year after surgery during a timed up and go test and a two times 50m walk using inertial sensors.

Surgical outcome parameters

Operation time, blood loss, and other relevant parameters in relation to the surgical procedures are registered. The cup and stem positioning are assessed using standard radiography in the first (hospital) days after surgery and at 1 year after surgery. A small subgroup of patients will undergo a CT or MRI scan.

Cost-effectiveness

Productivity costs, direct medical costs (costs of additional radiography, medical consumption) are assessed using questionnaires at 0, 3, 6, 9 and 12 months after surgery.

Study description

Background summary

Total hip arthroplasty (THA) is a surgical procedure in which the hip joint is totally replaced by a prosthetic implant and is one of the most frequently performed orthopaedic operations. There are several surgical techniques to approach the hip joint which differ in incision placement, tissue damage and postoperative management. The Direct Anterior Approach (DAA) is used more and more in performing THA. By using the DAA no muscles are damaged. There are indications in literature that this results in a shorter length of stay in the hospital, higher patient satisfaction and better cost-effectiveness when compared to the more standard Posterolateral Approach (PLA). The PLA requires a surgeon to detach several muscles before reaching the hip joint. This study aims to compare the clinical, functional and surgical outcome and cost-effectiveness of the DAA when compared to the PLA in total hip arthroplasty. The proposed study is a single centre, parallel group randomised clinical trial with balanced randomisation (1:1), and with a follow-up of one year after surgery. 120 patients aged over 18 years, suffering of osteoarthritis of the hip, who are a candidate for uncemented total hip arthroplasty will be included. The clinical outcome is defined in terms of pain and function of the hip in relation to different activities of daily life. Functional outcome will be assessed using several validated questionnaires. Surgical outcome, including operation time and blood loss, will be evaluated. A

cost-effectiveness analysis and budget impact analysis will be performed.

Study objective

With this study we will be able to determine whether the DAA has better short-term results compared to the PLA in THA whilst improving patient outcome and reducing costs for hospitals and society as a whole.

Study design

The proposed study is a single centre, with balanced randomisation (1:1), parallel group, partly single blinded, superiority study with a follow-up of 24 months after surgery conducted in Northwest Clinics Alkmaar.

Intervention

The intervention studied in the proposed project is the direct anterior approach (DAA) for total hip replacement surgery. The DAA is compared to the more standard used posterolateral approach (PLA). All operations are performed by three surgeons using a standard operating table. For the DAA, the patient is placed in a supine position. The hip capsule is reached from the front, utilizing the internervous plane, located between the sartorius muscle and tensor fascia latae muscle superficially, and between the rectus femoris muscle and gluteus medius muscle more profoundly. For the PLA, the patient is placed in the lateral position. The hip capsule is reached from the back, after incising the tensor fascia latae muscle and gluteal fascia, blunt dissection of the gluteus maximus muscle, and releasing the insertions of the piriformis, gemelli and obturator externus tendons.
For all operations the same hip prosthesis (Corail Hip System, DePuy Synthes, Warsaw, Indiana, United States of America) will be used, the size of which is chosen in accordance with the anatomical characteristics of each patient. If due to management decision there will be a change in prosthesis supplier, patients may be treated with the Polar total hip system (Smith and Nephew, Warsaw Indiana, united States of America). This stem has a similar tapered design.

Study burden and risks

Considering the fact that both intervention and control treatment are currently being performed as part of normal treatment procedures without any known increased risks for patients, we expect that the risk of participating in this study will be minimal. The burden of participating will consist of filling in questionnaires and undergoing walking test, and for a small number of patients (2x15) undergoing a CT or MRI scan, both regularly performed examinations.

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

• Willing and able to participate in the study protocol;
• Age between 18 and 80 years
• ASA Physical Status I, II and III
• Diagnosed with osteoarthritis of the hip
• Subjects for who it is decided that they will undergo an uncemented THA at Northwest Clinics Alkmaar

Exclusion criteria

• Patients with previous surgery to the ipsilateral or controlateral hip;
• Patients with posttraumatic changes of the pelvis or femur;

• Patients with inflammatory arthropathies;
• Patients diagnosed with osteoporosis
• Patients diagnosed with rheumatoid arthritis
• Patients who suffer from insulin dependant diabetes
• Patients who lack understanding of the Dutch language
• Patients who are treated for or diagnosed with neurological or muscle disorders which make assessment of pain and gait not possible

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:	Recruiting
Start date (anticipated):	04-08-2015
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	30-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2019
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL48411.094.14