COMparison of Posterolateral and direct Anterior approach in uncemented total hip arthroplasty with a Short Stem prosthesis

Published: 07-06-2017
Last updated: 15-05-2024

Primary Objective: The primary objective of this study is to investigate whether the NANOS femoral stem placed by means of the direct anterior approach (DAA) results in a better rigid fixation, stem position and off-set restoration at two years...

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

Summary

ID

NL-OMON46180

Source
ToetsingOnline

Brief title
COMPASS 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: Smith & Nephew,Stichting ALK-resort

Intervention

Keyword: anterior approach, hip replacement, posterolateral approach, short stem, subsidence

Outcome measures

Primary outcome

Radiographic analysis will be done on standard AP and lateral view X-rays postoperative, 8 weeks, 12 months and 24 months. Only the two X-rays that are taken during the extra outpatient appointment at 24 months do not include the standard treatment for THR. Migration and stem positioning analysis will be done using the EBRA-FCA system and is measured in mm.

Secondary outcome

Secondary study parameters are the clinical, functional and surgical outcome parameters compared between the DAA and PLA:

* Perceived pain, measured using a Visual Analogue Scale (VAS) in the week before surgery, during hospitalization at days 1 to 3, at discharge, 6 weeks, three months, six months, one year after surgery and two years after surgey.

* Hip pain and symptoms assessed using the symptoms, pain and activities of daily living (ADL) subscales of the Hip Dysfunction and Osteoarthritis Outcome Score (HOOS) in the week before surgery, at 6 weeks, three months, six months, one year after surgery and two years after surgey.

* Hip range of motion in the week before surgery, at 6 weeks, three months, six months, one year after surgery and two years after surgey.

* Quality of life assessed using the EQ-5D in the week before surgery, at 6 weeks, three months, six months, one year after surgery and two years after surgey.

* Functioning during daily living assessed using the HOOS in the week before surgery, at 6 weeks, three months, six months, one year after surgery and two years after surgey.

* Hip abductor strength and gait quality before surgery, at 6 weeks and after 12 months.

* Length of hospital stay

* Operation time, blood loss, and other parameters of the surgical procedures

* All complications related to the surgery and rehabilitation

* Health status will be classified using the ASA score.

* Patient*s pre-operative status, surgical procedure as well as clinical and radiological outcome will be documented.

8.1.3 Other study parameters

Patient characteristics such as age, gender, stature, body weight, body length, side of operation (left or right), smoking and comorbidities.

Study description

Background summary

Short-stems total hip prostheses, such as the NANOS prosthesis, pose possible advantages for active patients. Because a large part of the column femoris

remains intact it is possible to create a more anatomical reconstruction of the hip joint. This leads to better off-set restoration which may improve hip abductor function1,2. A reduced capacity of the abductor muscles might result in aberrant hip abduction/adduction pattern during walking, which might be problematic in for example the regulation of medio-lateral balance during walking. Another advantage in active patients is that the NANOS stem fixates proximally in the femur leaving more bone stock for a possible subsequent revision. Because of the proximal fixation it is suspected that the NANOS causes less stress shielding of the trochanter region3 and flexibility of the femur shaft is left intact leaving a natural capacity to bending forces on the femur shaft
The NANOS prosthesis was developed in 2002. Since its release positive results have been presented (table 1 and table 2) for complication rates and revision rates. Also, an ODEP 3A* rating was assigned in 2016.

The use of short stems corresponds with the trend of direct anterior and minimal invasive hip surgery we have seen last years. With these techniques more muscles are left intact and might therefore result in a better functional outcome, leading to shorter operation time, less perioperative complications and less muscle damage4. Thus, both the short stem total hip prostheses as well as the direct anterior and minimal invasive approaches in hip surgery can be considered relatively recent innovations in THA and both are aimed at improving functional and clinical outcome, mainly in the short term. However, the clinical and functional effectiveness of the combination, i.e. whether the use of short stem prostheses is even more effective when used during the direct anterior approach compared to when used during the regular posterolateral approach in THA, is as far as we know not yet investigated. Important parameters in THA which may be related to clinical and functional outcome are the level of fixation and positioning of the (short) stem, which are thought to be affected by surgical approach. In literature, it is well established that early migration (migration within two years after THA) of the stem is predictive for late aseptic loosening of the stem5,6. The computer-assisted Einzel-Bild-Roentgen-Analyse (EBRA) system was evaluated to detect stem migration of 1 mm with a specificity of 100% and a sensitivity of 78%7. This method is less invasive and easier to use in a clinical setting then the gold standard RSA method. A migration threshold of 1.5 mm after two years was found to be highly predictive for later aseptic loosening and significantly increased risk of revision 5. Comparing the level of migration of the short stem of the hip prosthesis for the direct anterior approach and the posterolateral approach in THA might add to the knowledge base of the effectiveness of the direct anterior approach and may help in evidence based clinical decision making when deciding for the best treatment option when a patient*s hip needs to be replaced.

Study objective

Primary Objective:

The primary objective of this study is to investigate whether the NANOS femoral stem placed by means of the direct anterior approach (DAA) results in a better rigid fixation, stem position and off-set restoration at two years follow-up in comparison with the NANOS stem placed using the posterolateral approach (PLA) in patients with hip osteoarthritis who need a total hip arthroplasty (THA).

Secondary Objectives:
The secondary objective is to compare THA with the short stem NANOS prosthesis using the DAA with the PLA for perceived pain, functioning of the hip, quality of life, isometric hip abduction force and quality of walking during the first two years after surgery.

Study design

This study will be a single center, randomized controlled clinical trial (RCT).
This study contains two arms, one with patients treated by means of the DAA and one with patients treated by means of the PLA.
Two surgeons will be participating in this study. Both are senior hip orthopedic surgeons for the NANOS prosthesis and both orthopedic surgeons can and will perform the DAA and the PLA. If the indication for primary hip arthroplasty is established, patients were asked if they wanted to participate. Patients who were interested in participating got an appointment with the research nurse after one week. Then informed consent was signed. Registry of data and block randomization will be executed via Castor.

As primary outcome we use the migration of the NANOS prosthesis in mm as measured with EBRA-FCA software. In addition, we will investigate functional outcome and quality of life with the HOOS and EQ-5D questionnaires.
Basic balance and gait performance will be tested using the timed *up & go* (TUG) test, instrumented with inertial sensors to measure body segment accelerations and angles, and a two times 50 meter walk at their preferred walking speed, also instrumented with inertial sensors8*12. For the TUG test13, in short, participants will be asked to stand up from a chair, walk for 3 meters, walk back to the chair and sit down on the chair. The time needed to perform the TUG test as instructed will be registered. In addition, the participants will wear validated inertial sensors (McRoberts Dynaport Hybrid, Dimensions 87 x 45 x 14 mm, Weight 74 grams)14, which will be attached to the lower back with Velcro fixation.
The study will take place between 2017 and 2020 in the Noordwest Ziekenhuisgroep location Alkmaar.

Intervention

Two surgeons will be placing the NANOS stems. Both surgeons will use the direct anterior approach (DAA) and the posterolateral approach (PLA). Both surgeons have extensive experience with both these approaches and previous experience

with the NANOS stem.

We will use a follow-up protocol that is similar to the NOV (Dutch orthopedic society) THA guidelines18. This protocol contains postoperative clinical and radiological visits at 6 weeks and one year. In addition, we will send patients functional evaluation questionnaire (HOOS, VAS) at 3 and 6 months. At 24 months we will schedule an additional clinical and radiological follow-up visit.

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 tests, and a single extra outpatient appointment and two x-rays two years after surgery.

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

Patient is willing and able to participate in the study protocol
Age between 18 and 75 years
ASA Physical Status I & II
Diagnosed with osteoarthritis of the hip
Subjects for who it is decided that they will undergo an uncemented THA at Noordwest Ziekenhuis Groep, location Alkmaar.

Exclusion criteria

Previous surgery to ipsilateral or contralateral hip.
Patient has proven osteoporosis
Pronounced coxa valga with a femoral neck angle > 145º
Pronounced coxa vara with a femoral neck angle < 125º
History of infection in the affected joint; systemic infections
Grossly insufficient femoral or acetabular bone stock in the involved hip where a revision cup is indicated
Spinal disease with neurologic movement disorders
Alcoholism or addictive disorders
Body mass index (BMI) > 30
Patients understanding of the language is insufficient for understanding the Patient Information and Consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2018
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO

Date:	07-06-2017
Application type:	First submission
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

ID: 21080
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL57624.094.16
OMON	NL-OMON21080