Comparison of posterolateral and direct anterior approach in uncemented total hip arthroplasty with a short stem prosthesis

Gepubliceerd: 18-09-2017 Laatst bijgewerkt: 15-05-2024

- The NANOS short stem prosthesis will show less subsidence if placed by means of the direct anterior approach (DAA) compared to the posterolateral approach (PLA) at two years follow-up - The NANOS short stem prosthesis will show better stem...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21080

Bron
Nationaal Trial Register

Verkorte titel
COMPASS

Aandoening

uncemented, total hip arthroplasty, short stem, posterolateral approach. direct anterior approach

Ongecementeerd, totale heupprothese, korte steel, posterolaterale benadering, direct anterieure benadering

Ondersteuning

Primaire sponsor: Noordwest Ziekenhuisgroep, locatie Alkmaar
Overige ondersteuning: Smith & Nephew Nederland CV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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 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). Also, stem position and off-set restoration will be taken into account.

Toelichting onderzoek

Achtergrond van het onderzoek

The purpose of this randomized controlled study is to compare posterolateral approach (PLA) and direct anterior approach (DA) in total hip arthroplasty with the NANOS short stem for subsidence, functional outcome, quality of life and isometric hip abduction force over a follow-up period of 2 years.

Doel van het onderzoek

- The NANOS short stem prosthesis will show less subsidence if placed by means of the direct anterior approach (DAA) compared to the posterolateral approach (PLA) at two years follow-up

- The NANOS short stem prosthesis will show better stem position if placed by means of the DAA compared to the PLA at two years follow-up

- The NANOS short stem prosthesis will show better off-set if placed by means of the DAA compared to the PLA at two years follow-up

- The NANOS short stem prosthesis will show lower pain scores if placed by means of the DAA compared to the PLA

- The NANOS short stem prosthesis will show a better functional outcome and range of motion if placed by means of the DAA compared to the PLA

- The NANOS short stem prosthesis will show higher maximum isometric hip abductor muscle force if placed by means of the DAA compared to the PLA

- The NANOS short stem prosthesis will show a better gait pattern in terms of hip joint angles

and hip joint moments in the frontal plain if placed by means of the DAA compared to the PLA

Onderzoeksopzet

Demographic characteristics - pre-operative

Clinical outcome:

HOOS - pre-operative, 8 weeks, 3 months, 6 months, 12 months, 24 months

VAS - pre-operative, day 1-3, 8 weeks, 3 months, 6 months, 12 months, 24 months

Hospital stay - day 1-3

EQ-5D - pre-operative, 8 weeks, 3 months, 6 months, 12 months, 24 months

Complications - pre-operative, day 1-3, 8 weeks, 3 months, 6 months, 12 months, 24 months

Functional outcome:

HOOS - pre-operative, 3 months, 6 months, 12 months, 24 months

HHS - pre-operative, 8 weeks, 12 months

Quality of balance and walking - pre-operative, 8 weeks, 12 months

Surgical outcome:

Operation parameters - Operation

Pelvic radiography - pre-operative, day 1-3, 8 weeks, 12 months, 24 months

Onderzoeksproduct en/of interventie

The NANOS short stem femoral component (Smith & Nephew, Memphis, Tennessee, United States of America) in combination with the R3 acetabular component (Smith & Nephew, Memphis, Tennessee, United States of America) will be placed. Both components are ODEP rated. The NANOS stem has previously been placed in the hospital in a research setting investigating short to medium survivorship and function and showed excellent results.

All patients will be submitted to standard postoperative physical therapy and analgesia protocols.

The prosthesis will be placed using a direct anterior or posterolateral approach. Both approaches are regularly performed in hospitals and clinics in the Netherlands and in Noordwest Ziekenhuisgroep location Alkmaar specifically. The two surgeons involved in the study have extensive experience with both approaches and perform at least 40 total hip replacements each year. Therefore, no specific surgical learning curve is expected for either of the procedures.

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.

The PLA is the most commonly used approach overall in the Netherlands. For the PLA, the patient is placed in the lateral position. The hip capsule is reached from the back, after incising the tensor fascia lata muscle and gluteal fascia, blunt dissection of the gluteus maximus muscle, and releasing the insertions of the piriformis, gemelli and obturator externus tendons.

Intra- and postoperatively patients will be treated according to the standard clinical hip replacement protocol implemented in the NWZ.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Willing and able to participate in the study protocol.

- Patient requires primary total hip replacement (THR) to the affected side, unilateral or bilateral.

- Patient agreed to participate in the study by signing the Informed Consent form.

- Age of patient at date of surgery 18 to 75 years.

- Patient is likely to comply with study follow-up requirements

- 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 Ziekenhuisgroep Alkmaar.

- Subjects who are able to give voluntarily, written informed consent to participate in this clinical investigation and from whom consent has been obtained.

- Subjects, who, in the opinion of the clinical investigator, are able to understand this clinical investigation, cooperate with the investigational procedures and are willing to return for all the required post-treatment follow-ups.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Previous surgery to ipsilateral or contralateral hip.

- Patients with posttraumatic changes of the pelvis or femur;

- Patients with inflammatory arthropathies;

- Patients diagnosed with rheumatoid arthritis

- Patients who suffer from insulin dependent diabetes

- Patients who are treated for or diagnosed with neurological or muscle disorders which make assessment of pain and gait not possible

- Patients who use medication for 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

- 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

- 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

- Patient is pregnant or being pregnant during follow up intervals

- Patients who lack understanding of the Dutch language

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2017
Aantal proefpersonen:	56
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-09-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46180
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6514
NTR-old	NTR6703
CCMO	NL57624.094.16
OMON	NL-OMON46180

Resultaten