SuperPath® - a pilot study

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It is hypothesized that it is feasible to perform Superpath in Reinier de Graaf hospital, Delft, The Netherlands

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22959

Bron
NTR

Verkorte titel
TBA

Aandoening

Total hip Arthroplasty for Osteoarthritis, Avascular necrosis (AVN), Inflammatory arthritis, Rheumatoid arthritis with adequate bone quality, Post-traumatic arthritis
or Congenital hip dysplasia.

Ondersteuning

Primaire sponsor: Department of orthopedic surgery
Overige ondersteuning: department of orthopedic surgery, Reinier de Graaf hospital Delft, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Feasibility will evaluated by the length of the operation, placement of the implants and blood loss during the individual procedure. 2 of the 3 criteria must be met, in order to consider the

surgery successful. Furthermore, if in 80% or more of the surgeries intra-operative complications (lesion of the n. Ischiadicus or a fissura of the femur) occur, the SuperPath procedure is not feasible.

- Surgery time for a primary total hip arthroplasty using SuperPath® may not exceed 2.5 hours.
- For the acetabular implant 20 to 60 degrees of inclination and 15 degrees of anteversion is accepted. The femoral implant should be placed straight in the femoral shaft and the hip rotation center should be restored anatomically
- The average amount of bloodloss performing total hip arthroplasty with SuperPath® may not exceed 1000 cc.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Cementless total hip arthroplasty (THA) has very good clinical results. As a result of the success, the ageing population and because the procedure is performed in increasingly younger and more active patients, the number of THA procedures has increased the last decades. Long term results of THA are well documented. Length of recovery after surgery and return to activities is thought to be affected by the surgical technique used. The supercapsular pecutaneously-assisted total hip (SuperPath®) surgical technique (MicroPort Orthopedics Inc., Arlington, TN, USA) is a new, promising technique. The advantage of SuperPath® is the tissue sparing aspect of the surgical approach. With this new technique, a new prosthesis is being used.
We would like to perform a pilot study on this new technique, in combination with the new prosthesis, in 10 patients.
Objective:
The primary objective of this study is to evaluate the feasibility of performing SuperPath® in the Reinier de Graaf Hospital in Delft.
Study design: A prospective pilot study in which 10cases will be enrolled over one hospital. Patients will be evaluated preoperatively and postoperatively at discharge (from operation date to date of discharge) at 6 weeks..
Study population: The study population consists of active male or non-pregnant female 18-75 years of age. The subjects have no clinical relevant disorders of the hip and they will undergo a hip arthroplasty after diagnosis of osteoarthritis, avascular necrosis (AVN), inflammatory arthritis, rheumatoid arthritis with adequate bone quality, post-traumatic arthritis or congenital hip dysplasia.
Intervention (if applicable): total hip arthroplasty with the supercapsular pecutaneously-assisted total hip (SuperPath®) surgical technique (MicroPort Orthopedics Inc., Arlington, TN, USA)
Main study parameters/endpoints: Outcome will be measured with several parameters. The feasibility of performing SuperPath® is the primary outcome which is measured by the length of the operation, the placement of the implants and the amount of bloodloss.

The outcome will be clinically measured using the HH, HOOS-PS, EQ5-D and OHS whilst radiographic outcomes will be evaluated through standard radiographic parameters. Complications will be monitored and registered during the follow up time of 6 weeks.

Doel van het onderzoek

It is hypothesized that it is feasible to perform Superpath in Reinier de Graaf hospital, Delft, The Netherlands

Onderzoeksopzet

preoperatively and 6 weeks after surgery

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patient is 18 to 75 years of age, inclusive
• Patient is able to speak and write Dutch
• Patient qualifies for primary unilateral total hip arthroplasty (THA) based on physical exam and medical history including at least one of the following:
o Osteoarthritis
o Avascular necrosis (AVN)

o Inflammatory arthritis
o Rheumatoid arthritis with adequate bone quality
o Post-traumatic arthritis
o Congenital hip dysplasia.

•Patient has no history of previous total hip replacement or arthrodesis of the affected hip joint(s).
• Patient is willing and able to provide written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects will be excluded when they meet one or more of the following contra-indications for the SuperPath® technique:
• Infection, sepsis, and osteomyelitis
• Patients with a low femoral offset
• Uncooperative patient or patient with neurologic disorders who are incapable of following directions
• Insufficient bone stock to provide adequate support and/or fixation to the prosthesis
• Metabolic disorders which may impair bone formation
• Osteomalacia
• Distant foci of infections which may spread to the implant site
• Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
• Vascular insufficiency, muscular atrophy, neuromuscular disease

Additionally, subjects will be excluded when they meet the following exlusion criteria:
• Patients with emergency or semi-emergency THA (e.g. for treatment of femoral neck fractures)
• Patient has a known or suspected sensitivity or allergy to one or more of the implant materials
• Revision THA surgery of the ipsilateral side
• Contralateral THA <6 months before current surgery

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-02-2019
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	08-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7512
Ander register	METC ZWH : 18-044

Resultaten