Persona Nederland

Gepubliceerd: 13-07-2017 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON25943

Bron
Nationaal Trial Register

Aandoening

Knee osteoarthritis, total knee prosthesis, total knee arthroplasty, knie artrose, totale knieprothese, totale knie arthroplastiek

Ondersteuning

Primaire sponsor: Department of Orthopaedics, Reinier de Graaf Groep
Overige ondersteuning: Zimmer Biomet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Implant survivorship based on removal of study device

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale

TKA has demonstrated effectiveness with substantive and sustained improvement in quality of life for individuals with moderate to severe osteoarthritis, however, functional performance in patients 1 year after TKA remains lower than for healthy adults, with reports of an 18% slower walking speed, 51% slower stair-climbing speed, and deficits of nearly 40% in quadriceps strength. Additionally, certain limitations in knee design systems require surgeons to accept compromises which can result in surgical inefficiencies and challenges in seizing desired outcomes. Patient expectations and an ever emerging population with active lifestyle also add a new requirement and need for innovative designs that bring advantages over traditional implants. Personalized implants with critical features of natural movement, contoured shape, and unique anatomic and physiologic composition can address these requirements.
This study will evaluate the commercially available Zimmer Persona knee implant used in primary total knee arthroplasty, a more personalized knee implant.

Objective

The primary objective of this study is to obtain implant survivorship and clinical outcomes data for commercially available Persona knee implants used in primary total knee arthroplasty.

Study design

A prospective multicenter, non-controlled study of commercially available Zimmer Persona knee implants will be enrolled. Patients will be evaluated preoperatively, during hospital stay and at 6 weeks, 1 year, 2,3,4, and 5 years post-operative.

Study population

The study population will consist of 200 patients who qualify for primary total knee arthroplasty and who meet the inclusion/exclusion criteria for study participation.

Intervention

The Zimmer Persona knee implant

Main study parameters/endpoints

1. Implant survivorship based on removal of a study device.

2. Safety based on incidence and frequency of adverse events.

3. Clinical performance measured by overall pain and function,

quality of life data, radiographic parameters and survivorship.

Onderzoeksopzet

Preoperative, during hospital stay, 6 weeks, 1 year, 2 years, 3 years, 4 years, 5 years

Onderzoeksproduct en/of interventie

total knee arthroplasty with the Zimmer Persona knee implant

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- Patiënt is 18-75 years of age

- Patient qualifies for a primary total knee arthroplasty based on physical exam and medical history, including diagnosis of severe knee pain and disability due to at least one of the following: a: Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis. b: Collagen disorders and/or avascular necrosis of the femoral condyle. c: Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy. d: Moderate valgus, varus, or flexion deformities. e: The salvage of previously failed surgical attempts that did not include partial or total knee arthroplasty of the ipsilateral knee.

- Patient is willing and able to complete scheduled study procedures and follow-up evaluations

- Independent of study participation, patient is a candidate for commercially available Zimmer Persona knee implants implanted in accordance with product labeling

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patient is currently participating in any other surgical intervention studies or pain management studies

- Previous history of infection in the affected joint and/or other local/systemic infection that may affect the prosthetic joint

- Insufficient bone stock on femoral or tibial surfaces

- Skeletal immaturity

- Neuropathic arthropathy

- Osteoporosis or any loss of musculature or neuromuscular disease that compromises the affected limb

- Stable, painless arthrodesis in a satisfactory functional position

- Severe instability secondary to the absence of collateral ligament integrity

- Rheumatoid arthritis accompanied by an ulcer of the skin or a history of recurrent breakdown of the skin

- Patient has a known or suspected sensitivity or allergy to one or more of the implant materials

- Patient is pregnant or considered a member of a protected population (e.g., prisoner, mentally incompetent, etc.)

- Patient has previously received partial or total knee arthroplasty for the ipsilateral knee.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
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:	01-11-2014
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-07-2017
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	NL6391
NTR-old	NTR6566
Ander register	14-071 : METC ZWH

Resultaten