Multicenter Prospective Randomized Control Study on Persona Total Knee System vs NexGen Total Knee System in Total Knee Arthroplasty

K.CR.I.EU.15.13

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Study Synopsis

TITLE	Multicenter Prospective Randomized Control Study on Persona Total Knee System vs NexGen Total Knee System in Total Knee Arthroplasty
PROTOCOL NUMBER	K.CR.I.EU.15.13 (RCT)
STUDY DESIGN	Multicenter, 2-arm, randomized, controlled, single-blinded post-market study
STUDY OBJECTIVES / ENDPOINTS	**Primary endpoint:** Evaluate patient reported outcome measures following primary total knee replacement using Persona Total Knee system compared to NexGen total Knee System as measured by: Oxford Knee Score (3 months, 1 and 2 years postoperatively) **Secondary endpoints:** • Evaluate patient reported outcome measures following primary total knee replacement using Persona Total Knee system compared to NexGen total Knee System as measured by: Oxford Knee Score -Activity & Participation Questionnaire (APQ) anchoring questions, EQ-5D and Forgotten Joint Score (3 months, 1 and 2 years postoperatively). • Evaluate intra-operative and postop complications as well as long-term survivorship following primary total knee replacement using Persona Total Knee system compared to NexGen total Knee System as follows: - Radiolucency / osteolysis at immediate postop 3 months, 1 and 2 year postoperatively. - Adverse Events including intraoperative complications and revisions at any post-operative time points. - Survival through registries at 5,7 and 10 years postoperatively.
INCLUSION/EXCLUSION CRITERIA	**Inclusion criteria:** • Patients with clinical and radiological osteoarthritis of the knee set to receive a primary unilateral total knee replacement • >18 years of age • Participants must be able to speak and understand Danish, able to give informed consent and be cognitively intact, able to complete all post-operative controls • Participants must not have severe comorbidities, ASA score ≤ 3 • Patients should be clinically suitable to receive a CR implant (no severe deformity and/or ligament instability) **Exclusion criteria:** • Terminal illness • Revision knee replacement surgery

	• RA • Traumatic etiology • Prior surgery on the affected knee that includes osteosynthesis, ACL and/or PCL and/or collateral ligament surgery. Arthroscopy with menisceotomy / cartilage surgery / house cleaning is allowed. • Altered pain perception and / or neurologic affection due to diabetes or other disorders. • Patients will be excluded intraoperative if CR implant is not suitable
SAMPLE SIZE	314 patients
LENGTH OF STUDY	Start/End-date: 2016 / 2029 (18 months enrolment, 2 years postoperative visits, up to 10 years postoperative follow-up in the registries)
INVESTIGATIONAL PRODUCTS	Persona Total Knee System NexGen total Knee System • Only cruciate retaining (CR) components will be used in this study. • Both cemented and cementless femoral components • Both standard as well as narrow femoral components • Only cemented tibial components • Conventional polyethylene will be used for patients >65 years old and Vitamin-E infused poly insert may be used for patients ≤ 65 years old. • Resurfacing of patella is performed in all cases.
SCORES/PERFORMANCE ASSESSMENTS	OKS, OKS-APQ, EQ-5D, FJS, Patient satisfaction, ROM, X-rays (AP/lateral)
STATISTICAL REPORTING	• Using a two-sided t-test, 90% power and SD =10, 266 patients would be required. Accounting for a 15% drop-out 314 patients are planned to be enrolled. • Non-inferiority analysis will be performed after 216 patients, based on OKS at one-year post randomization; MCID is set at 4 points. • Using a one-sided t-test, 90% power and SD =10, non-inferiority margin of 4 OKS, 216 patients would be required for the NI analysis. • The power calculation is based on reaching sufficient power when a comparison of the study groups is carried out.