ROSA Total Knee Post Market Study

A prospective, multicenter, EMEA post market clinical follow up of the ROSA® Knee System

CME2019-24K

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STUDY SPONSOR

Zimmer GmbH Clinical Affairs

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Study Synopsis

Title	ROSA Total Knee Post Market Study – a prospective, multi-center EMEA post market clinical follow up study for the ROSA Total knee system
Protocol Number	CME2019-24K
Sponsor	Zimmer GmbH
Manufacturer	Zimmer CAS, 75 Queen Street Suite 33000, Montreal, Quebec. Canada
Study Device(s)	ROSA® Knee System
Study Objectives/Endpoints	The main purpose of this study is to collect and compare clinical outcomes data using the commercially available ROSA Total Knee Robotic instrumentation and conventional instrumentation. This will be achieved by assessing: 1. Planned vs actual component positioning 2. Operative workflow efficiency 3. Patient safety based on incidence and frequency of adverse events 4. Clinical performance measured by overall pain and function, health- related quality of life data, and radiographic parameters. <u>Primary endpoint</u>: Evaluate the accuracy of implant alignment for ROSA total knee robotic instrumentation compared to conventional instrumentation, by measuring femoral rotation in the axial plane using pre op and post op CT assessments. <u>Secondary endpoints</u>: Measure operative workflow efficiency by recording following time points during surgery: Patient in –and out time, incision – and incision closed time Evaluate the change of the following scores between baseline and each post-operative follow up for performance and clinical benefits: • Oxford Knee Score • Objective Knee Assessment • Patient Satisfaction • EQ-5D • NRS Pain • FJS-12
Indications/Target population	Patients qualifying for primary total knee arthroplasty who meet the inclusion/exclusion criteria for study participation

Inclusion/Exclusion criteria	Inclusion criteria: • Patient is a minimum of 18 years of age • Independent of study participation, patient is a candidate for commercially available Persona, NexGen, or Vanguard knee components implanted in accordance with product labeling • Patient has participated in this study-related Informed Consent Process • Patient is willing and able to provide written Informed Consent by signing and dating the EC approved Informed Consent form • Patient is willing and able to complete scheduled study procedures and follow-up evaluations Exclusion criteria: • Patient is currently participating in any other surgical intervention studies or pain management studies • Patient has underwent contralateral UKA or TKA within the last 18 months • Hip pathology with significant bone loss (e.g. avascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum) • Hip pathology severely limiting range of motion (e.g. arthrodesis, severe contractures, chronic severe dislocation) • 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
Study Design	Prospective, multicenter study, using Zimmer Biomet commercially available Persona, NexGen and Vanguard total knee implant system. Each consecutive, potential and eligible patient presenting as a candidate for primary knee arthroplasty will be offered study participation. Selection process should be rotated on an equal basis. (eg. 5 Robotic TKA's followed by 5 Conventional TKA's and so on until enrolment is complete)
Clinical Phase	Post market
Sample Size	Maximum 8 EMEA sites, with participating surgeons contributing from 20 of each robotic and conventional knees per site. Maximum study enrolment of 240 subjects in total, including 40 subjects in the CT sub cohort
Length of Study	2,5 years (1,5 year enrolment with 1 year of follow-up). Follow-up visits at 6 weeks, 3 months and 1 year.

Materials and Methods	Inclusion of 240 eligible subjects within maximum of 8 EMEA sites, divided into 2 groups (robotic and conventional group). Sub cohort of 40 subject for CT assessment and analysis Prospective follow up visit until 1 year post-operative with clinical and radiographic assessments.
Data Collection	Web based database (Electronic data capture system)
Statistical Reporting	Performance will be evaluated for pain, function, health- related quality of life, and planned component position vs post-op component position. Data will be summarized descriptively additional to evaluation of data on surgical technique and instrumentation. Categorical data (e.g., gender or race) will be summarized using counts and percentages with 95% Confidence Interval (CI) limit over the time period of interest. Continuous data, such as age, will be summarized by using means, medians, SD, minimum, maximum, and 95% CI over the time period of interest. Implant survival and return to function will be summarized using a Kaplan-Meier method and presented with rates (as percentages) and CI. Routine summaries of complication data is represented by frequencies and percentages. The sample size is based on a longitudinal data collection model and using functional outcomes as secondary endpoints. The data from the CT sub cohort will detect for a difference in deviation from the initial alignment target proportions and presented with rates (as percentages) and CI. Continuous data from pre and post-operative CT measurement will be summarized by using means, medians, SD, minimum, maximum and 95% CI over the time period of interest.
Scores/Performance Assessments	Clinical performances are assessed by the following scores: • Oxford Knee Score • Objective Knee Assessment • Patient Satisfaction • EQ-5D • NRS Pain • FJS-12 Radiographic performances are assessed by: • Radiographicimaging method pre- and post-operatively • Sub cohort for CT scan pre- and post-operatively
Standards	The PMCF is compliant with the below: • The Declaration of Helsinki (DoH) - Ethical principles for medical research involving human subjects. [1] • ISO 14155: 2011 - Clinical investigation of medical devices for human subjects - Good clinical practice. [2]

References

[1] WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI, Ethical Principles for Medical Research Involving Human Subjects, Version October 2013.

[2] ISO 14155:2011 International Standard for Clinical investigation of medical devices for human subjects -- Good clinical practice.