CLINICAL INVESTIGATION PLAN

Prospective, multi - centre clinical evaluation of the performance and safety of the HYPERION hip endoprosthesis system in defect reconstruction

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STUDY SPONSOR

Zimmer GmbH
Sulzerallee 8
P.O. Box
CH-8404 Winterthur
Switzerland

Study Summary

Title:	Prospective, multi - centre clinical evaluation of the performance and safety of the HYPERION hip endoprosthesis system in defect reconstruction
Sponsor:	Zimmer GmbH
Objectives/ Endpoints	The data collected from this post-market clinical follow up study will serve the purpose of confirming long-term safety and performance of the Hyperion system. To this aim, the Hyperion system will be evaluated using standard scoring systems, radiographs and the reporting of adverse events. Patients having received the Hyperion hip replacement stem will be followed up after 1 week, 3 month, 6 month, 1, 2 and 5 years assessing clinical and radiographic outcomes. In addition, after 7- and 10- years the patients will be asked to fill in a questionnaire recording the patients mid-to long-term clinical satisfaction. Primary endpoints: 1. Merle d'Aubigné score Endpoint: Merle d' Aubigné Score increase of min. 4 points at 2 years post surgery, compared to the pre-operative score points (< 12 points). 2. Implant survival at 2 years (+/- 2 months) 3. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores Endpoint: Decrease in min. 25 points in the WOMAC Score compared to the pre-operative determined points (WOMAC Score > 25 points pre-operative). The primary outcome measure is at 2 years (+/- 2 month).
Indication/ Target Population:	Patients, suffering from severe hip pain and disability requiring total hip arthroplasty, who meet the inclusion/exclusion criteria
Study Design:	Multi-center, prospective, non-controlled
Clinical Phase:	Post-market
Number of Subjects:	A total of 70 patients will be enrolled

Length of Study:	12 years
Study Device:	Hyperion System
Clinical Assessments	Merle d`Aubigné Score, WOMAC scores and radiographic assessments.
Safety Assessments:	Safety will be assessed by appropriate recording and reporting of adverse events throughout the study. All system components are CE marked and commercially available.
Statistical Analysis	Data collected will be summarized and reported to each participating Investigator. Statistical analysis is conducted by Zimmer or its designee.

General Statistical Method:

Data collected in the study will be summarized descriptively. Descriptive summaries will be used for the basis of all study reports, including a summary of the clinical performance of the HYPERION hip endoprosthesis system in defect reconstruction, and may be used for reports and to support presentations and publications as needed.
Summaries will routinely describe categorical data as counts and percentages, and ninety-five percent confidence limits will be generally used to assess differences over time. Routine summaries describing continuous data will be in the form of means, medians, standard deviations, minima, and maxima, and ninety five percent confidence intervals will be used to contrast differences.
Routine summaries of implant survival will be described using the Kaplan-Meier method.
Routine summaries of complication data will be in the form of frequencies and percentages.
Summaries may be further generated for strata within the study population, such as males/females, body mass index or primary diagnosis.