FitmoreTM Hip Stem Post-Market Clinical Follow-Up (PMCF) Study

Protocol number: 09H06
Protocol date: November 2, 2010. Revision 2
NCT number: NCT03411044

1 STUDY SYNOPSIS

Complete Protocol Title	A multi-centre, non-comparative, prospective post-market clinical follow-up study to obtain survival, clinical and radiographic outcomes data on the Zimmer FitmoreTM Hip Stem.
Protocol Number	09H06
Short Protocol Title	Fitmore PMCF
Sponsor	Zimmer GmbH
Manufacturer	Zimmer GmbH
Study Device(s)	FitmoreTM Hip Stem
Study Objectives/Endpoints	The objective of this study is to obtain survival, clinical and radiographic outcomes data on the Zimmer FitmoreTM Hip Stem by analysis of standard scoring systems and radiographs.
Indications/Target Population	Patients suffering from severe hip pain and disability requiring total hip arthroplasty.
Inclusion/Exclusion Criteria	***Inclusion Criteria*** • Patients who are capable of understanding the doctor‟s explanations, following his instructions and who are able to participate in the follow-up program. • Patients who have given written consent to take part in the study by signing the „Patient Consent Form‟. • 18 years minimum. • Male and female. • Patients suffering from severe hip pain and disability requiring hip surgery or as indicated in the treatment of a fracture. ***Exclusion Criteria*** • Patients who are unwilling or unable to give consent or to comply with the follow-up program. • Pregnancy. • Patients who are skeletally immature.
Study Design	A multi-centre, non-comparative, prospective post-marketing study
Clinical Phase	Post-market
Sample Size	500

Length of Study	Collection of preoperative, intra-operative and immediate post-operative data; follow-up visits at 6-12 weeks, 1, 2, 3, 5, 7 and 10 years post-operatively. Recruitment period: 24 months.
Materials and Methods	Case report forms will be completed either in-office or hospital at Pre-op, Surgery, Discharge, and the 6 week, 1 year, 2 year, 3 year, 5 year, 7 and 10 year intervals.
Data Collection	Paper/Electronic
Statistical Reporting	Data collected will be summarized and reported to each participating investigator. Statistical analysis will be conducted by Zimmer Biomet or its designee.
Scores/Performance Assessments	Evaluations will be made using the Harris Hip Score, the Oxford Hip Score, the SF-12 Physical and Mental Health summary measures, the EQ-5D (EuroQol) and radiographically.
Standards	The PMCF is compliant with the below: • ISO 14155 Standard for the Clinical Investigation of Medical Devices (part 1 and 2) [1][2].
Study Funding	Funding for this clinical study is made available by Zimmer Biomet to support clinical data collection, IRB/EC review fees and other expenses associated with the conduct and execution of this study protocol as outlined in the fully executed Clinical Trial Agreement.

2 STATISTICAL ANALYSIS PLAN

Statistical Considerations

Data collected in the study will be summarized. Descriptive summaries will be the basis of study reports to participants. Summaries will routinely describe categorical data as counts and percentages, and describe continuous data in the form of means, medians, standard deviations, minima, and maxima.

Summaries of variables such as implant survival, return to function or time to event will generally be described via the Kaplan-Meier method and will be accompanied with the corresponding rates (expressed as percentages). Complication data will be summarized 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.