GTS

A prospective study to evaluate long-term clinical outcomes of the GTS® cementless femoral stem

NCT02851992

TITLE	A prospective study to evaluate long-term clinical outcomes of the Global Tissue Sparing GTS® cementless femoral stem
AIMS	The objective of this prospective clinical study is to obtain multi-center, long-term (10-year) clinical data on the new GTS® femoral stem in its standard and lateralized versions as part of Post Market Surveillance requirements
DESIGN	This is a multicenter, non-controlled, prospective study. 250 subjects (GTS standard and lateralized) will be recruited. Study will be conducted in 5 centers across Europe (Germany, Italy, Spain, France)
OUTCOME MEASURES	**Primary Outcome Measure for all study patients** • Mean Harris Hip Score (HHS) at 2 year postoperative **Secondary Outcome Measures for all study patients** • Radiographic Evaluation: stability, incidence of radiolucencies around the prosthesis and bone remodeling • Patient satisfaction: EQ5D quality of life • Adverse Events/Complications (including revisions/removals). • Survivorship
POPULATION	250 subjects suitable for GTS femoral stem (standard and lateralized) can be included
ELIGIBILITY	**Inclusion criteria** Patients inclusion criteria for this evaluation are be in accordance with the indications of the GTS® stem and specifically • Primary osteoarthritis or secondary coxarthritis • Inflammation of the hip: rheumatoid arthritis, etc. • Femoral neck fracture • Avascular necroses of the femoral head • Sequelae from previous operations on the hip, osteotomies, etc. • Congenital hip dysplasia Additional inclusion criteria include: • 18 years of age or older • Subjects willing to return for follow-up evaluations • Subjects who read, understood study information and provided an informed written consent (specific local regulatory requirements) **Exclusion criteria** Exclusion criteria are in accordance with absolute and relative contraindications for use for GTS® stem Absolute contraindications include: • Local or systemic infections. • Severe muscular, neurological or vascular deficiencies of the extremity involved • Bone destruction or poor bone quality that is likely to affect implant stability (Paget's disease, osteoporosis, etc.) • Concomitant disease likely to affect implant function • Allergy to any of the components of the implant • Patients weighing more than 110 kg Additional exclusion criteria: • Subjects unable to co-operate with and complete the study • Dementia and/or inability to understand and follow instructions • Neurological conditions affecting movement • Patient over 18 under law supervision

DURATION	The initial study assessment period will be 12 years; 24 months recruitment and the follow-up clinical reviews for all patients will be at 3 months, 1 year, 2 years, 3 years, 5 years, 7 years and 10 years.

1. STATISTICAL ANALYSIS PLAN

Data will be recorded in a case report form on the basis of one CRF per patient. For bilateral procedures, one CRF per joint must be completed.

Statistical analysis will be performed on an intent-to-treat basis, using for all data the SPSS software (SPSS, Chicago, Illinois). For qualitative variables, the chi-square test and a Fisher test will be performed to detect differences between preoperative and postoperative values. The Student t test will be employed for quantitative variables for comparison between groups.

1.1. SAMPLE SIZE CALCULATION

Patient population was determined based on mean Harris Hip Score (HHS) at 2 years follow-up.

Sample size calculation was led as follows:

$$N = \frac{4 \times STD2 \times (Z)^2}{(X - Y)^2}$$

Where:

STD = Standard Deviation
X-Y = Margin of Error or Precision
Z = Z1-α/2

In order to determine Harris Hip Score with 95% confidence: then Z = 1.96
If HHS is between 95 to 100: then X=100 and Y=95
Estimate standard deviation of HHS at follow-up = 13
This value has been based on results from previous studies (Reference 1)

$$N = \frac{4 \times (13)2 \times (1.96)^2}{(100 - 95)^2}$$

N = 104
With attrition rate of 15%
Starting population = N/0.85 = 104/0.85 = 122 rounds to 125 subjects in GTS standard group.

The same calculation applied to GTS varized group.

1.2. DETAILED DESCRIPTION OF RANDOMIZATION

NA

1.3. HANDLING OF MISSING AND INCOMPLETE DATA

1.3.1. Per Protocol (PP) Population

Patients who have complete data collected per the protocol are the Per Protocol (PP) population.

1.3.2. Intent to Treat (ITT) Population

Patients who have met the Inclusion/Exclusion criteria and have signed the Informed Consent will be tracked. Those patients that dropped-out of the study and did not receive the investigational or control treatment will be accounted with documentation for the specific reason for not receiving the investigational or control device. Accountability for all patients that

have received the investigational or control device but have not completed all follow-up examinations will be tracked using the methods described in “Handling of Missing Data”.

1.3.3. Sensitivity Analysis

A sensitivity analysis will be performed to assist in explaining both clinically and statistically the pooling of those patients (ITT population) with missing outcome data with those patients who have complete data collected per protocol (Per Protocol (PP) population). The analysis will compare the study results based on both populations and ensure that the handling of missing data does not cause bias on the overall study conclusion.

1.3.4. Handling of Missing Data

It is most important to minimize missing data by retaining patients and obtaining complete data at all required follow-up intervals. According to the Intent Treat (ITT) principle, all patients’ missing data will be tracked and treated.

1.4. DATA ANALYSES

1.4.1. Interim analysis

Annual Progress Report - The evaluator must submit a yearly progress report to Biomet and the ethical committee summarizing his preliminary clinical results.

1.4.2. Final

Final Report - The evaluator must make a final report of his clinical results upon completion of the evaluation. This report is submitted to Biomet and the ethical committee. The data from all evaluations will be collected and final Report will be produced; all evaluators shall sign this report, or if any evaluator does not sign a justification shall be provided.