1.0 INTRODUCTION

1.1 STUDY RATIONALE

Lower back pain (LBP) is a significant cause of morbidity, with an annual prevalence ranging from 15-45% of people [1]. A contributor to lower back pain is the sacroiliac (SI) joint, and an estimated 15-30% of LBP is derived from issues with this joint [2, 3]. In patients with SI joint pathology who fail conservative management, SIJF provides effective pain relief [4, 6], even when compared to optimized conservative management [7-12]. This is a multi-site, prospective, single arm feasibility study.

1.2 Risk/Benefit Assessment

This is an approved device in use for sacroiliac joint fusion in a real world setting and therefore there is no more risk than standard of care.

2.0 OBJECTIVES

Primary Objective: To evaluate the effectiveness of the treatment with Siros SI Joint Fusion System

Primary endpoints:

- Assessment of improvement in SI Joint Pain using the NRS
- Assessment of improvement in Back Dysfunction using the ODI
- # Patients with Serious SAEs
- Assessment of improvement in Quality of Life (PROMIS 10)

3.0 STUDY DESIGN

3.1 Overall Design

This is a prospective, single arm, post-market feasibility pilot study that will include at least five sites for recruitment and enrolment. A minimum of 35 eligible subjects with a diagnosis of degenerative sacroiliitis or sacroiliac joint disruption who meet inclusion/exclusion criteria and are intended to be treated via sacroiliac joint fusion will be enrolled in this study. No placebo or control will be utilized during this study.

4.0 STUDY POPULATION

4.1 Inclusion Criteria

- Age 21-80 at time of screening
- Patient has lower back pain for >6 months
- Baseline Oswestry Disability Index (ODI) score of at least 30%

4.2 Exclusion Criteria

- Severe back pain due to other causes
- Other known sacroiliac pathology
- History of recent (<1 year) major trauma to pelvis
- Previously diagnosed and uncorrected osteoporosis

4.3 Strategies for Recruitment and Retention

Recruitment will be competitive, and to minimize selection bias, consecutive patients meeting pre-defined eligibility criteria will be enrolled. The study team and study coordinator will be informed about all patients who present a diagnosis of degenerative sacroiliitis or sacroiliac joint disruption; these patients will be reviewed by appropriate members of the study staff immediately to determine eligibility for participation in the study.

5.0 STUDY INTERVENTION

5.1 Study Intervention Description

The Genesys Spine Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions. It is FDA cleared under a 510(k) number K191748.

6.0 STUDY ASSESSMENTS AND PROCEDURES

6.1 Safety

AEs, SAEs, and SUSARs will be assessed for severity, relationship, and seriousness.

7.0 STATISTICAL CONSIDERATIONS

Numbers and percentages and where applicable mean, median, minimum and maximum as well as standard deviation and interquartile range will be described. 95% confidence intervals will be calculated.

8.0 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

8.1 Consent

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study intervention.

8.2 Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participants.

8.3 Data Handling and Record Keeping

Study documents should be retained for a minimum of 2 years. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the FDA.

8.4 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, International Conference on Harmonization Good Clinical Practice (ICH GCP), requirements. The noncompliance may be either the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

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