CASE STUDY

Versius Surgical Robotic System - COL

STUDY DESCRIPTION

A Prospective Clinical Study to Evaluate the Safety and Efficacy of the Versius Surgical System in Robot-Assisted Cholecystectomy

STUDY OBJECTIVE

Evaluation of the Safety and Efficacy of the Versius Surgical Robotic System in robotically assisted Cholecystectomy surgical procedures. Measured by incidence of serious adverse events and successful completion of the surgery without conversion to laparoscopic or open surgery, respectively.

PATIENT POPOLATION

Sample size of 30 patients

All patients suitable for Robot assisted- minimal access Cholecystectomy surgeries using Versius® above 18 years of age.

PRIMARY EFFICACY AND SAFETY PARAMETERS

Efficacy has been measured by the rate of successful completion of the procedures as planned (i.e., without unplanned conversion to other laparoscopic or open surgery). Meanwhile safety has been measured by the rate of incidence of serious adverse events up to 30 days following procedure.

STUDY DETAILS

Monocentric (1 Polish site)
Total number of patients: 30
Recruitment period: 44 days
First patient in (LPI): June 26, 2023
Last patient in (LPI): August 9, 2023.
Last patient last visit (LPLV): September 11, 2023

SINTESI RESEARCH SERVICES

Project management, regulatory, site coordination, CRA meetings, data management, QA QC, medical final report, safety management.

KEY CHALLENGES

- Short time to perform the trial;
- Goal: FDA submission by December 2023;
- The fast recruitment has required a very high performing data management enabling the customer to have in a very short time clean data;
- The fast recruitment and assurance of high standard data quality also required close and frequent monitoring activities.

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KEYS OF PROJECT SUCCESS

- Site activation 2 days after receiving full regulatory approval for the study; (EC final approval 13 June 2023 ans SIV 16 June 2023)
- To ensure fast recruitment and high standard data quality Sintesi Research team performed a very tight monitoring activity (2 Site Initiation Visit, 8 Interim Monitoring Visit and 1 Close Out Visit) within 2 months;
- To keep constantly update the sponsor about study ongoing status Sintesi Research gave priority on team communication performing biweekly teleconferences with client;
- Sintesi Research team worked closely with the clinical site encouraging the investigators to complete enrolment, fill in the data base and helping site staff to perform all procedures study related;
- 1 month after DB closure delivery of final safety and statistical report of the study;
- Achievement of FDA submission in December 2023 by the Sponsor.

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