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Study to evaluate the safety and efficacy of the Versius surgical system in robot-assisted total hysterectomy (a surgical procedure to remove your womb)

Submission date
13/04/2023

Recruitment status
No longer recruiting

Registration date
13/04/2023

Overall study status
Completed

Last Edited
13/04/2023

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Minimal access surgery (also known as keyhole surgery) has been carried out for over 30 years at hospitals around the world. It is well-established and has several advantages over other surgical methods, such as a shorter recovery time, fewer complications and a shorter hospital stay. Thousands of minimal access operations are carried out each year. Recently it has been possible to use robot arms to help carry out minimally invasive operations.
This study is being run to assess the safety and competence of the Versius® Surgical Robotic System in performing operations for the removal of the womb in females. Versius is a robot designed to be used in minimal access surgery. It has been developed and built by CMR Surgical Limited, a UK-based and registered company. The system allows a surgeon to stand or sit at a console to control a set of robotic arms which are holding instruments needed to perform minimal access surgery.

Who can participate?
Non-pregnant female patients aged 18 years and above who are eligible for womb removal surgery with Versius, as decided by the operating surgeon

What does the study involve?
All participants will have womb removal surgery as usual and as decided by their healthcare professionals.

What are the possible benefits and risks of participating?
There are no direct benefits to participants. The information collected may benefit patients in the future, however, the expected benefits of surgery with Versius include a minimized risk of injury due to improved surgical precision, a lower risk of infection, bleeding and pain, earlier discharge from hospital and smoother recovery, compared to open surgery. The risks of participating in this study are similar to those associated with any minimal access (keyhole) womb removal surgical procedure and will be explained in detail before surgery.

Where is the study run from?
CMR Surgical (UK)

When is the study starting and how long is it expected to run for?
July 2022 to November 2023

Who is funding the study?
CMR Surgical (UK)

Who is the main contact?
Dr Mark Slack, mark.slack@cmrsurgical.com

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CA-00374

Study information

Scientific Title
Prospective clinical study to evaluate the safety and efficacy of the Versius surgical system in robot-assisted total hysterectomy

Acronym
VCSTLH-Poland

Study objectives
The Versius surgical system is safe and efficacious in performing robot-assisted total hysterectomies

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/10/2022, Ethics Committee of The Medical University of Silesia in Katowice (Ul. Poniatowskiego 15, 40-055 Katowice, Poland; +48 (0)322083546; kombioet@sum.edu.pl), ref: PCN/CBN/0052/KB1/100/I/22

Primary study design
Interventional

Study design
Prospective non-randomized single-arm clinical trial cohort

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Robot-assisted total hysterectomy

Interventions
A prospective single-arm cohort study for robot-assisted total hysterectomies with the Versius Surgical Robotic System. Use of Versius, patient care and all follow-ups (up to day 42 +/-2 days) will be as per standard clinical practice, and Good Clinical Practice (GCP) and regulatory requirements will be strictly followed.

Intervention Type
Device

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Versius Surgical Robotic System

Primary outcome(s)
Primary safety outcome:
Incidence of serious adverse events, recorded on the data entry platform at any time between commencement of surgery (intraoperative) to the end of the trial (postoperative, between the incidence of surgery to 30 days after surgery)

Primary efficacy outcome:
Rate of successful completion of robot-assisted surgery without unplanned conversion to other laparoscopic or open surgery, as recorded on the data entry platform

Key secondary outcome(s)

1. Operative time measured in minutes from incision to skin closure at the facility, collected as procedural data from medical records
2. Estimated blood loss (in ml) during surgery, collected as procedural data from medical records
3. Blood transfusion during surgery (number of blood transfusion products used [if any]) collected from patient's medical records
4. Any intra-operative complications during surgery collected as procedural data and from the patient's medical records
5. Return to the operating room within 24 hours after surgery, measured using medical records
6. Length of hospital stay in days (from date of procedure to date of discharge), measured using medical records
7. Incidence of readmission to hospital within 30 days after surgery, measured using medical records and at 30-day follow-up
8. Incidence of reoperation within 30 days after surgery, measured using medical records and at 30-day follow-up
9. 30-day mortality from medical records and/or follow-up visit/call during the 30-day follow up
10. Vaginal vault healing, as assessed and recorded by the surgeon on medical records at the clinic on 42 days postoperative follow-up
11. Histopathology results of any surgically removed specimens from medical records available on the day of discharge and at 30 days follow up
12. Incidence of device deficiencies and use errors regardless of relationship to an adverse event, collected as procedural and/or adverse event data and from patient medical records, between intraoperative period until discharge
13. All adverse events, including postoperative complications reported using Clavien-Dindo Classification and according to medical records, up to 30 days' follow up
14. Device performance data including unplanned instrument usage, clashes, collision detection, alarms, collected as procedural data during surgery

Completion date
01/11/2023

Eligibility

Key inclusion criteria
1. Patient deemed suitable for total laparoscopic hysterectomy procedure using the Versius Surgical Robotic System
2. Patients able to provide written informed consent to participate in the study (with help of appropriate legal representatives if required)
3. Females aged 18 years or above
4. Females of childbearing potential must not be pregnant
5. Patients with BMI ≤40 kg/m². Ideally BMI ≥25 to ≤40 kg/m²

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Patient participation in an investigational clinical study within 30 days before screening
2. Inability or difficulties to provide informed consent
3. Uncontrolled hypertension (≥systolic: 180 mmHg/diastolic: 120 mmHg)
4. Diabetes mellitus (glycemia >11 mmol/l; >200 mg/dl)
5. Oncological cases, patients undergoing surgery or treatment for malignant disease
6. Patients who fall into American Society of Anaesthesiologists (ASA) Class IV or above
7. Uterus size of >14 weeks
8. History of chronic alcohol or drug abuse
9. Chronic renal failure or on dialysis
10. Significant medical history or immunocompromised
11. Subjects with any other clinically significant unstable medical disorder, life-threatening disease, or anything else in the opinion of the Investigator which would contra-indicate a surgical procedure
12. Patient tested COVID positive within the last 30 days of screening
13. Patient tested COVID positive within 48 hours of the procedure

Date of first enrolment
01/05/2023

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
Poland

Study participating centre
Uniwersyteckie Centrum Kliniczne im. prof. K. Gibińskego Śląskiego Uniwersytetu Medycznego w Katowicach
Medyków 14
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Sponsor information

Organisation

CMR Surgical (United Kingdom)

ROR
https://ror.org/00nq5xx94

Funder(s)

Funder type
Industry

Funder Name
CMR Surgical

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date