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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
27/10/2022

Recruitment status
No longer recruiting

Registration date
03/11/2022

Overall study status
Completed

Last Edited
28/10/2022

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 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 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 a console to control a set of robotic arms which are holding instruments needed to perform minimal access surgery.

Who can participate?
All non-pregnant female patients aged 18 years and above, eligible for 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. The risks from participating in this study are similar to those associated with any minimal access (keyhole) womb removal surgical procedure.

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

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

Who is funding the study?
CMR Surgical (UK)

Who is the main contact?
Dr Mark Slack
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Contact information

Type(s)
Principal investigator

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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CA-00361

Study information

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

Acronym
V.C.S.-TLH

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 11/08/2022, Manavata Clinical Research Institute Ethics Committee (Mumbai Naka, Nashik-422002, India; +91 253-6661111; mpec.nashik@gmail.com), ref: ECR/500/Inst/MH/2013-RR20

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

Primary study design
Interventional

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 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 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 patient's medical records
5. Return to 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 recoded by surgeon on medical records at the clinic on 42 days post operative follow up
11. Histopathology results of any surgically removed specimens from medical records available at day of discharge and at 30 day 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
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
31/03/2023

Eligibility

Key inclusion criteria
1. Patient deemed suitable for total laparoscopic hysterectomy procedure using 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. Female, aged 18 years or above
4. Female 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 >11mmol/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, lifethreatening disease, or anything else in the opinion of the Investigator which would contra-indicate a surgical procedure
12. Patient tested COVID positive within last 30 days of screening
13. Patient tested COVID positive within 48 hours within procedure

Date of first enrolment
17/11/2022

Date of final enrolment
01/01/2023

Locations

Countries of recruitment
India

Study participating centre
HCG Manavata Cancer Centre
Behind Shivang auto
Mumbai Naka
Nashik
Maharashtra

Mumbai
India
422002

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes