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

Submission date 13/10/2022	Recruitment status No longer recruiting	Prospectively registeredProtocol
Registration date 20/10/2022	Overall study status Completed	 Statistical analysis plan Results
Last Edited 20/10/2022	Condition category Surgery	 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 stays. 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 gall bladder. 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 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 gall bladder 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) gall bladder 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 January 2023

Who is funding the study? CMR Surgical (UK)

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

Study website

http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=72325&EncHid=&userName=CTRI/2022/08/045073

Contact information

Type(s) Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers CA-00358, CTRI/2022/08/045073

Study information

Scientific Title

Prospective clinical study to evaluate the safety and efficacy of the Versius surgical system in robot-assisted cholecystectomy

Acronym

VCSCCE

Study objectives

The Versius surgical system is safe and efficacious in performing robot-assisted cholecystectomies.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 12/08/2022, Institutional Ethics Committee, Devki Devi Foundation (Service Floor, Office of Ethics Committee, East Block, Max Super Speciality Hospital, Saket 2, Press Enclave Road, Saket, New Delhi, 110017, India; +91 9873003832; Kamal.Fotedar@maxhealthcare.com), ref: CT/MSSH/DDF/SKT-2/IEC/MAMBS/22-08

Study design

Prospective non-randomized single-arm clinical trial cohort

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Robot assisted cholecystectomy

Interventions

A prospective single arm cohort study for robot assisted laparoscopic cholecystectomy, with the Versius Surgical Robotic System. Use of Versius, patient care and all follow-ups 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 measure

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

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)

Secondary outcome measures

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. Histopathology results of any surgically removed specimens from medical records available at day of discharge and at 30 day follow up

11. 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 12. All adverse events, including postoperative complications reported using Clavien-Dindo

Classification and according to medical records, up to 30 days' follow up 13. Device performance data including unplanned instrument usage, clashes, collision detection, alarms, collected as procedural data during surgery

Overall study start date

01/03/2022

Completion date

01/01/2023

Eligibility

Key inclusion criteria

1. Patient deemed suitable for laparoscopic Cholecystectomy 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. Male and Female, aged 18 years or above

4. Female of childbearing potential, must not be pregnant and agree to not become pregnant for the duration of the study

5. Patients with BMI <40 kg/m². Priority BMI 25 to 40 kg/m²

Participant type(s)

Patient

Age group Adult

Lower age limit 18 Years

Sex

Both

Target number of participants

30

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. Oncological cases, Patients undergoing surgery or treatment for malignant disease
- 4. Patients who fall into American Society of Anaesthesiologists (ASA) ClassIV or above
- 5. History of chronic alcohol or drug abuse
- 6. Chronic renal failure or on dialysis
- 7. Significant medical history or immunocompromised

8. 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

- 9. Patient tested COVID positive within last 30 days of screening
- 10. Patient tested COVID positive within 48 hours day the of the procedure

11. Diabetes mellitus (Glycemia > 11mmol/L ; >200 mg/dL) 12. Uncontrolled hypertension

Date of first enrolment 17/10/2022

Date of final enrolment 01/12/2022

Locations

Countries of recruitment India

Study participating centre Max Super-Specialty Hospital 2 Press Enclave Road Saket New Delhi India 110017

Sponsor information

Organisation CMR Surgical (United Kingdom)

Sponsor details 194 Cambridge Science Park Milton Road Cambridge England United Kingdom CB4 0AB +44 1223 755300 customer.service@cmrsurgical.com

Sponsor type

Website https://cmrsurgical.com/

Industry

ROR https://ror.org/00ng5xx94

Funder(s)

Funder type Industry

Funder Name CMR Surgical

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed journals. The researchers are not planning on making the protocol publicly available at this time.

Intention to publish date 10/10/2023

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