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A database to record safety information from patients who have had surgery using the Versius Surgical Robotic System

Submission date 11/09/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/10/2019	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/01/2021	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
CMR Surgical, a medical device company based in Cambridge, UK, has designed and built Versius, a new surgical robotic system. Surgeons use Versius to complete a laparoscopic surgical procedure (keyhole surgery) by sitting at the surgeon console, next to the patient in the operating room but away from the operating table. The surgeon looks at a screen and uses hand controllers to control the surgical instruments. At the bedside, small, wheeled carts (bedside units) are positioned by the operating room staff. Each bedside unit holds a robotic arm which either holds a camera or surgical instrument for the procedure. This type of surgery, where surgeons and operating room teams interact with Versius to complete an operation is sometimes known as robotically assisted surgery.
To monitor how safe Versius is for patients, CMR surgical has launched a surgical registry (the CMR Surgical Registry). The registry will also provide a database of how surgeons are using Versius. The registry will collect important information about every operation a surgeon performs using Versius. For example, the information will include what operation was carried out, how long it took, and how the patient recovered afterwards. CMR Surgical is asking every hospital and surgeon who uses Versius to take part in the registry and collect information from every operation they carry out. The registry is important to CMR Surgical because the company takes its responsibility for patient safety very seriously. By law, surgical device companies must monitor the safety of devices such as Versius. The company also wants to use the information in the registry to help them make changes to Versius and how surgeons use it - these changes may benefit patients in the future. CMR Surgical also wants to support and promote academic research to make robot-assisted surgery even safer.

Who can participate?
All patients eligible for surgery with Versius, as decided by the operating surgeon.

What does the study involve?
All potential participants will have surgery as usual and as decided by their healthcare professionals. To participate, the patient must agree that their surgeon can provide information to the registry, including information collected relevant to the operation in their medical records.

What are the possible benefits and risks of participating?
There are no direct benefits to individual patients by participating in the registry. The information collected may benefit patients in the future. There are no risks to providing information to the registry. Surgical risks will be explained by the surgeon and will be the same whether the patient participates in the information collection or not..

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

When is the study starting and how long is it expected to run for?
January 2019 to April 2025

Who is funding the study?
CMR Surgical (UK)

Who is the main contact?
Mark Slack, registry@cmrsurgical.com

Contact information

Type(s)
Scientific

Contact name
Dr Mark Slack

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CMR Surgical Registry

Study information

Scientific Title
CMR Surgical Registry

Study objectives
Current study hypothesis as of 26/01/2021:
The registry will enable post-market surveillance and safety monitoring of the Versius Surgical Robotic System.

Previous study hypothesis:
The registry will enable post-market surveillance and safety monitoring of the Versius Surgical Robotic System, as well as record how surgeons use the system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The registry is a post-marketing surveillance database, collecting data about a new device used in routine clinical practice. It is not research and therefore does not require ethics approval.

Study design
Prospective, observational, multi-centred registry

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Robot-assisted surgery, including urological, general, gynaecological, and thoracic laparoscopic surgical procedures

Interventions
Current interventions as of 26/01/2021:
The Versius Surgical Robotic System is licensed for use in urologic surgical procedures, general laparoscopic surgical procedures, gynaecologic laparoscopic surgical procedures and thoracic laparoscopic surgical procedures. Peri-operative data will be collected from all consenting patients undergoing an operation performed with Versius by their surgeon or surgical team. Data will be collected from patient medical records at the time of surgery and up to 90 days post-operative follow-up. The registry has been designed to collect information that is commonly recorded in the peri-operative environment for all surgical procedures.

Previous interventions:
The Versius Surgical Robotic System is licensed for use in urologic surgical procedures, general laparoscopic surgical procedures and gynaecologic laparoscopic surgical procedures. Peri-operative data will be collected from all consenting patients undergoing an operation performed with Versius by their surgeon or surgical team. Data will be collected from patient medical records at the time of surgery and up to 90 days post-operative follow-up. The registry

has been designed to collect information that is commonly recorded in the peri-operative environment for all surgical procedures.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Intra- or post-operative complications recorded in the patient’s medical records up to 90 days post-surgery

Key secondary outcome(s))
1. Rate of conversion to another surgical method identified during surgery
2. Operative time recorded during surgery as recorded in patient medical records
3. Length of hospital stay as measured as time from admission to date of discharge recorded in patient medical records
4. Return to OR within 24 h as recorded in patient medical records
5. Readmission to hospital within 30 days as recorded in patient medical records
6. 90-day mortality as recorded in patient medical records

Completion date
30/04/2025

Eligibility

Key inclusion criteria
Any patient eligible for surgery using the Versius Surgical Robotic System as determined by their surgeon

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
02/03/2019

Date of final enrolment

31/01/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

France

India

Study participating centre
Deenanath Mangeshkar Hospital & Research Centre
c/o Dr Dhananjay Kelkar
Erandawne
Pune
Maharashtra
Pune
India
411004

Study participating centre
HCG Manavata Cancer Centre
Mumbai Naka
Nashik
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422002

Study participating centre
Western General Hospital
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Study participating centre
Milton Keynes University Hospital
Milton Keynes University Hospital NHS Foundation Trust
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MK6 5LD

Sponsor information

Organisation
CMR Surgical Limited

Funder(s)

Funder type
Industry

Funder Name
CMR Surgical Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from registry@cmrsurgical.com. Data requests will only be accepted from academics, clinicians or research institutions and will be assessed by the Clinical and Medical Affairs Team and independent Registry Steering Committee. Persons wishing to submit a request to access a dataset from the registry must provide a detailed project plan explaining which data is requested and for what reasons. Data may only be released once further anonymised, grouped, and evidence of ethics permission obtained. Data request functions will only be available from 2020.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v5.0	17/09/2019	08/10/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes