

# Versius clinical study to evaluate the safety and performance of the Versius Surgical Robotic System

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
05/08/2021	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
25/08/2021	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
23/08/2021	Surgery	<input type="checkbox"/> 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 look at the use of the new robot arm system in minimal access surgery known as the Versius® Surgical Robotic System. Versius is a new 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 between 18 and 65 years old eligible for surgery with Versius, as decided by the operating surgeon.

### What does the study involve?

All participants will have 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) 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?

February 2019 to July 2022

Who is funding the study?  
CMR Surgical (UK)

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

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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### Type(s)

Public

### Contact name

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### Contact details

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
CA-00014

# Study information

## Scientific Title

A prospective clinical study to evaluate the safety and performance of the Versius Surgical Robotic System

## Acronym

VCS

## Study objectives

The Versius Surgical Robotic System is safe and effective in robotically-assisted surgery across multiple surgical procedures.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Approved 23/02/2019, Institutional Ethics Committee Deenanath Mangeshkar Hospital & Research Center (Erandawne, Pune 411004, India; +91 (0)20 4015 1000/49153000, iec@dmhospital.org), ref: ECR/15/Inst/Maha/2013/RR-19
2. Approved 11/08/2020, Ethics Committee, Rao Nursing Home, Pune (Satara Rd, Bibwewadi, Pune, Maharashtra 411037, India, +91 (0)20 – 24526800; ecrnh2017@rediffmail.com), ref: ECR /597/Inst/MH/2014/RR-20
3. Approved 11/10/2019, Manavata Clinical Research Institute Ethics Committee (Nashik Near Mylan Circle, Mumbai Naka, Nashik, Maharashtra 422002, Nashik, India; +91 (0)253-6661111; mpec.nashik@gmail.com), ref: ECR/500/Inst/MH/2013/RR-20
4. Approved 30/11/2020, Ethics Committee Down Town Hospital (Swagat Super Speciality Hospital, Sankardev Path  
Dispur, GS Road, Guwahati, 781006, Assam, India; +91 (0)361 2331003; ethicscommittee@downtownhospital.in), ref: ECR/549/Inst/AS/2014/RR-17

## Study design

Multi-centre prospective non-randomized single-arm clinical trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Robotically assisted surgery in patients requiring general, gynaecological, urological and colorectal surgical and minimal access procedures

## Interventions

The Versius Surgical Robotic System is used for robotic-assisted surgeries in the fields of:

1. General surgery – cholecystectomy, appendectomy, bilateral inguinal hernia (TAPP), gastric, esophagectomy, Nissen fundoplication, hiatus hernia, and diagnostic laparoscopic procedures
2. Gynaecology – total laparoscopic hysterectomy (TLH), salpingectomy (unilateral or bilateral), salpingo-oophorectomy, unilateral or bilateral oophorectomy, ovarian cystectomy for benign

disease, diagnostic laparoscopic procedures, radical hysterectomy, Burch colposuspension, sacro-colpopexy, sacro-hysteropexy  
3. Urology – non-functioning nephrectomy, radical nephrectomy, partial cystectomy, radical cystectomy and renal cyst decompression  
4. Colorectal – right hemicolectomy, abdominoperineal resection, and lower anterior resection

## **Intervention Type**

Device

## **Phase**

Phase II/III

## **Drug/device/biological/vaccine name(s)**

Versius Surgical Robotic System

## **Primary outcome(s)**

Primary effectiveness outcome:

Rate of conversion to other laparoscopic or open surgery intraoperatively, as recorded on the data entry platform by the surgeon

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 90 days after surgery)

## **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. Return to operating room within 24 hours after surgery, measured using medical records
5. Length of hospital stay in days (from date of procedure to date of discharge), measured using medical records
6. Incidence of readmission to hospital within 30 days after surgery, measured using medical records and 30-day follow-up calls/visit
7. Any intra-operative complications during surgery collected as procedural data and from patient's medical records
8. Postoperative complications reported using Clavien-Dindo Classification up to 90 days
9. 90-day mortality from medical records and/or follow-up visit/call during the 90-day follow up

## **Completion date**

01/07/2022

## **Eligibility**

### **Key inclusion criteria**

1. Patient deemed suitable for at least one of the surgical procedures using Versius
2. Patients (or appropriate legal representatives) able to provide written and audio-visual informed consent to participate in the study
3. Male or female aged between 18 and 65 years old

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

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patient participation in an investigational clinical study within 30 days before screening
2. Inability to provide informed consent
3. Uncontrolled hypertension (=/>systolic: 180 mmHg/diastolic: 120 mmHg) and/or diabetes mellitus (blood sugar level: >200 mg/dl)
4. Patients who fall into American Society of Anesthesiologists (ASA) Class IV
5. History of chronic alcohol or drug abuse
6. Chronic renal failure or on dialysis
7. Significant medical history or immunocompromised and/or chronic use of systemic steroids
8. Patients undergoing surgery or treatment for malignant disease
9. Subjects with any other clinically significant unstable medical disorder, life-threatening disease, or anything else in the opinion of the Investigator which would contraindicate a surgical procedure

**Date of first enrolment**

04/03/2019

**Date of final enrolment**

01/12/2021

## Locations

**Countries of recruitment**

India

**Study participating centre**

**Deenanath Mangeshkar Hospital & Research Centre**

Erandawane, Maharashtra

Pune

India

411004

**Study participating centre****HCG Manavata Cancer Centre**

Nashik Near Mylan Circle, Mumbai Naka, Maharashtra  
Nashik  
India  
422002

**Study participating centre****Healing Hands Clinic**

4th Floor, Millenium Star Extension Adjacent to Ruby Hall Entrance Gate  
Dhole Patil Rd, Maharashtra  
Pune  
India  
411001

**Study participating centre****Swagat Super Specialty Surgical Institute**

Maligaon, Guwahati, Assam  
Assam  
India  
781009

## **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?
<a href="#"><u>Participant information sheet</u></a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#"><u>Study website</u></a>	Study website	11/11/2025	11/11/2025	No	Yes