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

Submission date
05/08/2021

Recruitment status
No longer recruiting

Registration date
25/08/2021

Overall study status
Completed

Last Edited
23/08/2021

Condition category
Surgery

[ ] 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 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

Study website
http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=31768&EncHid=&userName=versius

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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
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 measure
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)

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. 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

Overall study start date
23/02/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
645

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
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India
781009

Sponsor information

Organisation
CMR Surgical (United Kingdom)

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Sponsor type
Industry

Website
https://cmrsurgical.com/

ROR
https://ror.org/00nq5xx94

Funder(s)

Funder type
Industry

Funder Name
CMR Surgical

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journals. The researchers are not planning on making the protocol publicly available at this time.

Intention to publish date
01/07/2023

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