Clinical Trial Details (PDF Generation Date :- Thu, 17 Aug 2023 05:20:59 GMT)

CTRI Number	CTRI/2023/03/050470 [Registered on: 07/03/2023] - **Trial Registered Prospectively**
Last Modified On	07/03/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Medical Device
Study Design	Single Arm Study
Public Title of Study	Borns Robotic Surgery System Clinical Study
Scientific Title of Study	Pilot Study Clinical Trial to Evaluate the Safety and Efficacy of Robotic Surgery System for Minimum Access Surgical Procedures

Secondary IDs if Any

Secondary ID	Identifier
CI/MD/2023/000005	DCGI
CTP-IND-20220924 (version: v1.0 date: 24/09/2022)	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Vivek Bindal
Designation	Head of Department
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Details Contact Person (Scientific Query)

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Details Contact Person (Public Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Max Hospital Vaishali

Primary Sponsor

Primary Sponsor Details	
Name	Max Hospital Vaishali
Address	Max Hospital Vaishali W-3, Sector-1, Vaishali, Ghaziabad, 201012, U.P.
Type of Sponsor	Private hospital/clinic

Details of Secondary Sponsor

Name	Address
Borns Medical Robotics Inc	6325 Tucker Dr, San Jose, CA 95129 USA

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Vivek Bindal	Max Speciality Hospital Vaishali	Department, Institute of Minimal Access, Bariatric and Robotic Surgery. 4th Floor tower 1 Room No 4 , Max Hospital Vaishali (A Unit of crosslay remedies limited)W-3, Sector-1, Vaishali, Ghaziabad, 201012, U.P. Ghaziabad UTTAR PRADESH	91-99999-31958 bindal.vivek@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
IEC Max Super Speciality Hospital, Vaishali	Approved	12/12/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	23/02/2023

Health Condition / Problems Studied

Health Type	Condition
Patients	Diseases of the digestive system
Patients	Overweight, obesity and other hyperalimentation

Intervention / Comparator Agent

Type	Name	Details
Intervention	BMR-5000 Surgical Robot	The main system includes Surgical Cart, Control Console, Lens Drive Robot, Tool Drive Robot, and Equipment Cabinet. The main system operates the robotic instrument to complete the operation. The intended use of the BMR-5000 Surgical Robot is for precise control of key technical operations such as tissue clipping, sharp

		dissection, blunt dissection, tissue exposure, cutting, suturing, hemostasis, and digestive tract reconstruction in minimally invasive surgery.
Comparator Agent	NIL	NIL

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	75.00 Year(s)
Gender	Both
Details	Patients who meet the surgical indications and need minimally invasive cholecystectomy, appendectomy, abdominal hernia repair, bariatric or gastrointestinal surgery.Volunteered to participate in this trial and signed the informed consent.

Exclusion Criteria

Exclusion Criteria	
Details	1. Those who cannot tolerate or establish pneumoperitoneum. 2. Severe heart, lung, liver, and kidney disease who cannot tolerate surgery. 3. Those who need emergency surgery due to illness. 4. History of continuous systemic corticosteroid or immunosuppressive therapy within the past 1 mon. 5. The patient is mentally incapable to understand the requirements and consequences of the study. 6. Pregnant and lactating women. 7. The patient is unwilling or unable to comply with the doctor orders. 8. Those who have participated in clinical trials within the past three months. 9. Extremes of age (Less than 18 years or more than 75 years) 10. Other conditions deemed inappropriate by the PI and medical staff.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Incidence of adverse events, serious adverse events, and complications (i.e., surgery-related adverse events, device defects) Surgical success rate, which is the rate between the cases completed without unplanned change in surgical treatment (such as conversion to conventional laparoscopic /open surgery) and the total number of cases.	Before surgery (Day -30) Operation period (Day 0) 24 hours after surgery Postoperative (Day 3) Postoperative (Day 7) After surgery (Day 14) Postoperative (Day 30)

Secondary Outcome

Outcome	Timepoints
operation time, intraoperative blood loss, device performance, physical status score (ECOG), cost analysis, etc.	Operation period (Day 0) 24 hours after surgery Postoperative (Day 3) Postoperative (Day 7) After surgery (Day 14) Postoperative (Day 30)

Target Sample Size

Total Sample Size=20
Sample Size from India=20
Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials

	Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	10/03/2023
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**2 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	Trial Title - Pilot Study Clinical Trial to Evaluate the Safety and Efficacy of Robotic Surgery System for Minimum Access Surgical Procedures Design - This study applies a single-center, single-arm clinical trial design, to include 20 subjects. Subjects who met the inclusion criteria of this study will be enrolled in the study for surgical treatment using the device. Site - Max Super Speciality Hospital, Vaishali (A Unit of Crosslay Remedies Limited) Sample Size - 20 Cases and the specific procedures are Cholecystectomy (5 cases), appendectomy or abdominal hernia repair (5 cases), gastrointestinal surgery (10 cases) including, bariatric surgery, and gastrointestinal tumors surgery. Scope - Patients who meet the indications for general surgery and intend to undergo minimally invasive surgery. (Such as cholecystectomy, appendectomy or abdominal hernia repair, gastrointestinal tumor, etc.) Indications - This device is used for precise control of key technical operations such as tissue clipping, sharp dissection, blunt dissection, tissue level exposure, cutting, suturing, hemostasis, nerve exposure, and protection, and digestive tract reconstruction in minimally invasive surgery, and assists in the completion of general surgery Minimally invasive surgery, etc. Purpose - This clinical investigation plan specifies a Pilot Study Clinical Trial to evaluate the efficacy and safety of a laparoscopic robotic surgical system produced by Borns Medical Robotics Inc., for minimally invasive surgery operations. The main clinical safety and efficacy evaluation endpoint of this trial is defined as: Primary Safety Outcome - Incidence of adverse events, serious adverse events, and complications (i.e., surgery-related adverse events, device defects) Primary Efficacy Outcome - Rate of successful completion of robotic assisted surgery without unplanned conversion to laparoscopic/open surgery. Secondary Efficacy Evaluation - operation time, intraoperative blood loss, device performance, physical status score (ECOG), cost analysis, etc.