ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: May 29, 2024

ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID:	IIT2023015
Brief Title:	Comparison of Short-term and Long-term Outcomes of Robotic and Laparoscopic Right Colon Cancer: a 10-year Single-center Large-sample Retrospective Study
Official Title:	the Ethics Committee of the First Affiliated Hospital of Nanchang University
Secondary IDs:	

Study Status

Record Verification:	May 2024
Overall Status:	Completed
Study Start:	December 1, 2014 [Actual]
Primary Completion:	March 31, 2024 [Actual]
Study Completion:	April 30, 2024 [Actual]

Sponsor/Collaborators

Sponsor:	Taiyuan Li
Responsible Party:	Sponsor-Investigator Investigator: Taiyuan Li [tli] Official Title: the First Affiliated Hospital of Nanchang University Affiliation: Nanchang University
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Exempt
Data Monitoring:	

Study Description

Brief Summary:	The goal of this observational study is to evaluate the short-term outcomes and long-term outcomes of robot-assisted right colon group for cancer compared

to laparoscopic-assisted right colon group. This is a large sample study based on ten years of clinical data. The main question it aims to answer is: What are the advantages of da Vinci robot right hemicolectomy compared to laparoscopic right hemicolectomy, and is there a difference in long-term efficacy between the two methods.

Detailed Description:

Conditions

Conditions: Robotic, Laparoscopic, Colon Cancer, Short-term Outcomes, Long-term Outcomes

Keywords:

Study Design

Study Type: Observational

Observational Study Model: Cohort

Time Perspective: Retrospective

Biospecimen Retention:

Biospecimen Description:

Enrollment: 1879 [Actual]

Number of Groups/Cohorts: 2

Groups and Interventions

Groups/Cohorts	Interventions
robot-assisted right colon group Robot assisted radical surgery for right colon cancer	Device: Da Vinci Robot Surgical System Performing surgery on right colon cancer patients using the da Vinci robotic surgical system or laparoscopic surgical system Other Names: • Laparoscopic surgical system
laparoscopic-assisted right colon group Laparoscopic assisted radical surgery for right colon cancer	Device: Da Vinci Robot Surgical System Performing surgery on right colon cancer patients using the da Vinci robotic surgical system or laparoscopic surgical system Other Names: • Laparoscopic surgical system

Outcome Measures

Primary Outcome Measure:

1. overall survival
   [Time Frame: months]
2. disease-free survival

[Time Frame: months]

Secondary Outcome Measure:

3. the rate of postoperative complications
   [Time Frame: rates]
4. operative time
   [Time Frame: minute]
5. estimation of blood loss
   [Time Frame: ml]
6. number of retrieved lymph nodes
   [Time Frame: Number]
7. days after postoperative hospital stay
   [Time Frame: day]
8. time to first exhaust
   [Time Frame: hours]
9. time to liquid diet
   [Time Frame: hours]
10. the rate of intracorporeal anastomosis
    [Time Frame: rates]

Eligibility

Study Population:	The consecutive cases of robotic-assisted or laparoscopic-assisted right colectomy between December 2014 and March 2024. All cases derived from the First Affiliated Hospital of Nanchang University.
Sampling Method:	Non-Probability Sample
Minimum Age:	18 Years
Maximum Age:	85 Years
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:1) age: 18-85 years; 2) no distant metastasis; 3) preoperative colonoscopy showing that the tumor was located in the ileocecal region, ascending colon, hepatic flexure, or transverse colon with pathology showing malignancy; 4) signed informed consent. - Exclusion Criteria:1) multiple primary colorectal cancer; 2) recurrent right colon cancer; 3) preoperative neoadjuvant chemotherapy; 4) emergency surgery for intestinal obstruction, bleeding or perforation; 5) incomplete data and missing follow-up data. -

Contacts/Locations

Central Contact Person:	Taiyuan Li, doctor Email: ndyfy00530@ncu.edu.cn
Central Contact Backup:	shanping Ye, doctor

Email: ndyfy08807@ncu.edu.cn

Study Officials:

Locations:

IPDSharing

Plan to Share IPD: Undecided
Access to the database can be obtained from the corresponding author on reasonable request.

References

Citations:

Links:

Available IPD/Information: