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Fluorescence-guided lymphatic mapping in colorectal cancer

Submission date 17/06/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/06/2025	**Overall study status** Completed	
Last Edited 17/06/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Colorectal cancer is one of the most common types of cancer around the world. During surgery to remove the cancer, doctors also take out nearby lymph nodes to check if the cancer has spread. This helps guide further treatment. The study looked at whether using a special fluorescent dye called indocyanine green (ICG) during surgery could help doctors find and remove more lymph nodes compared to standard surgery without the dye.

Who can participate?
Patients who were diagnosed with left-sided colorectal cancer and were scheduled for planned (elective) surgery at Peking University People's Hospital between April 2018 and January 2020 were eligible to take part.

What does the study involve?
Participants had one of two types of surgery:
-One group had standard keyhole (laparoscopic) surgery.
-The other group had the same surgery, but with the addition of ICG dye. The dye made the lymphatic system glow under a special camera, helping surgeons see and remove lymph nodes more clearly.
Doctors then compared the number of lymph nodes removed and other surgical outcomes between the two groups.

What are the possible benefits and risks of participating?
Using ICG may help surgeons remove more lymph nodes accurately, which could improve cancer treatment and outcomes. The dye is generally very safe, with only a small chance of allergic reactions or other side effects. All procedures were part of standard medical care.

Where is the study run from?
Peking University People's Hospital in Beijing, China.

When is the study starting and how long is it expected to run for?
August 2018 to January 2020.

Who is funding the study?
The study was supported by the National Natural Science Foundation of China, along with other institutional and regional funding sources.

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2018PHB052-01

Study information

Scientific Title
Indocyanine green fluorescence-guided lymphatic mapping and navigated lymphadenectomy in colorectal cancer

Study objectives
We hypothesize that indocyanine green (ICG) fluorescence-guided lymphatic mapping and navigated lymphadenectomy improves the accuracy and completeness of lymph node dissection in left-sided colorectal cancer surgery compared to conventional laparoscopic approaches, potentially leading to improved oncological outcomes and more precise anatomical localization of lymphatic drainage.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/02/2018, Ethical Review Committee of Peking University People's Hospital (Xizhimen #11, Xicheng District, Beijing, 100044, China; +86 88324516; rmyyllwyh@163.com), ref: 2018PHB052-01

Study design
Prospective comparative cohort study with propensity score matching

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
ICG-guided lymphadenectomy in left-sided colorectal cancer

Interventions
• ICG-Guided Group (Experimental Arm): Patients received real-time indocyanine green (ICG) near-infrared fluorescence imaging-guided central lymph nodes mapping and dissection during laparoscopic radical resection. ICG was injected into the submucosa around the tumor one day before surgery via colonoscopy. Lymphatic drainage was visualized intraoperatively with a fluorescence camera.
• Control Group (Standard Arm): Patients underwent conventional laparoscopic radical resection without the use of ICG guidance.
• Intervention Duration: The surgery was conducted as a one-time procedure.
• Follow-up: All patients were followed up for a minimum of 36 months postoperatively to monitor recurrence and survival outcomes.

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Indocyanine green fluorescence mapping

Primary outcome(s)
Number of central lymph nodes harvested, measured by pathological examination of surgical specimens postoperatively at day 0

Key secondary outcome(s))
1. Total number of lymph nodes retrieved, measured via pathological analysis (postoperative day 0)
2. Surgical safety, assessed by intraoperative and postoperative complication rate within 30 days, based on clinical records and follow-up visits
3. 3-year disease-free survival (DFS), measured by clinical and radiological follow-up at regular intervals (every 3–6 months)
4. 3-year overall survival (OS), assessed through hospital records and follow-up calls at 36 months

Completion date
31/01/2020

Eligibility

Key inclusion criteria
1. Age between 18 and 85 years
2. Pathologically confirmed left-sided colon or rectal adenocarcinomas
3. Legal competence

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
85 years

Sex
All

Total final enrolment
251

Key exclusion criteria

1. Coexisting untreated malignancies
2. Medically contraindications to laparoscopic surgery
3. Known allergy to ICG or iodine
4. Impaired liver function

Date of first enrolment
01/08/2018

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
China

Study participating centre
Peking University People's Hospital
Xizhimen #11, Xicheng District
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Sponsor information

Organisation
Peking University People's Hospital

ROR
https://ror.org/035adwg89

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
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IPD sharing plan summary
Available on request