ISRCTN17907053 https://doi.org/10.1186/ISRCTN17907053

Indocyanine green fluorescence imaging in laparoscopic gastric cancer surgery: a safe and effective method to locate and remove tumors

Submission date
10/06/2025

Recruitment status
No longer recruiting

Registration date
12/06/2025

Overall study status
Completed

Last Edited
23/01/2026

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Stomach cancer is one of the most common and deadly cancers worldwide. Surgery is often the best way to treat it, and a newer, less invasive method called laparoscopic surgery is becoming more popular. However, this method can make it harder for surgeons to see and feel exactly where the tumor is, which can lead to removing more of the stomach than necessary. This study looks at whether using a special dye called indocyanine green (ICG), which glows under a special light, can help surgeons better see the tumor and remove it more precisely. The goal is to see if this technique is safe and effective.

Who can participate?
Adults aged 18 to 75 with stomach cancer who are scheduled for laparoscopic surgery to remove part of their stomach can take part. Both men and women are eligible.

What does the study involve?
Participants receive an injection of the ICG dye around the tumor before surgery. This helps the surgeon see the tumor more clearly during the operation. All other treatments are the same as usual. The study compares results from patients who receive the dye with those who don't, to see if the dye helps improve surgery outcomes.

What are the possible benefits and risks of participating?
The main benefit is that the surgery might be more accurate, helping to preserve more of the stomach and improve recovery. The main risk is a rare allergic reaction to the ICG dye, but this dye has been safely used for many years.

Where is the study run from?
Qilu Hospital of Shandong University (China)

When is the study starting and how long is it expected to run for?
Patients were enrolled between July 2019 and December 2021. The study includes a follow-up period of three years, which ended in December 2024.

Who is funding the study?
The study is funded by a research project at Shandong University (China)

Who is the main contact?
Yize Liang, liangyize1@163.com

Contact information

Type(s)
Principal investigator

Contact name
Prof Wenbin Yu

Contact details
107 Wenhuaxi Road
Jinan
China
250012
+86 18560085155
wenbin_yu2003@163.com

Type(s)
Public

Contact name
Dr Yize Liang

Contact details
107 Wenhuaxi Road
Jinan
China
250012
+86 17660440802
liangyize1@163.com

Type(s)
Scientific

Contact name
Prof Zhibo Yan

Contact details
107 Wenhuaxi Road
Jinan
China
250012
+86 18560085166
zhiboyan@sdu.edu.cn

Additional identifiers

Study information

Scientific Title
Safety and efficacy of indocyanine green fluorescence imaging in laparoscopic distal gastrectomy for gastric cancer: a randomized clinical trial

Study objectives
Using indocyanine green (ICG) fluorescence imaging during laparoscopic surgery for gastric cancer will improve the accuracy of tumor localization and resection, leading to better surgical outcomes and potentially higher survival rates.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/07/2019, Ethics Committee of Qilu Hospital of Shandong University (107 Wenhuaxi Road, Jinan, 250012, China; +86-531-82169166; qlyykyc@163.com), ref: 2019085

Primary study design
Interventional

Study design
Single-center interventional open-label randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improvement of tumor localization and reduction of positive resection margin in laparoscopic distal gastrectomy for gastric cancer

Interventions
Current interventions as of 15/09/2025:

For patients who are assigned to the ICG group, endoscopic ICG injection was performed one day before surgery. ICG (Dandong Yichuang Pharmaceutical Co., Ltd) was dissolved in sterile water at a concentration of 0.625 mg/ml, and 0.5 mL ICG solution was injected into the submucosa of the stomach at four sites around the primary tumor, respectively.
Tumor is localized based on the guidance of ICG fluorescence, and the stomach is transected along the proximal fluorescent edge to remove the tumor.
A minimum of 3-year follow-up was achieved.

Randomization:
1. Eligibility & Enrollment
Eligible participants meeting inclusion/exclusion criteria will be assigned unique Study IDs (001-410). Due to the open-label nature, participants will be informed about group allocation post-randomization
2. Randomization Setup

Allocation ratio: 1:1 (205 in ICG Group vs 205 in Control Group)
Method: Computer-generated simple randomization sequence using R statistical software (sample() function)
Validation: Sequence will be verified by independent biostatistician
3. Implementation
System: Interactive Web Response System (IWRS) with real-time allocation
Timing: Performed immediately after completion of baseline assessments
Notification: Instant electronic notification to site investigators; Participants receive allocation information during the same visit
4. Quality Control
Audit Trail: Complete timestamped randomization records maintained
Balance Monitoring: Weekly checks of allocation ratios
5. Documentation
CRF will prominently display "OPEN-LABEL STUDY" header
All randomization documents archived as "UNBLINDED MATERIALS"
Protocol will state: "Due to the nature of interventions, this study employs an open-label design"

———

Previous interventions:

For patients who are assigned to the ICG group, endoscopic ICG injection was performed one day before surgery. ICG (Dandong Yichuang Pharmaceutical Co., Ltd) was dissolved in sterile water at a concentration of 1.25 mg/ml, and 0.5 mL ICG solution was injected into the submucosa of the stomach at four sites around the primary tumor, respectively.
Tumor is localized based on the guidance of ICG fluorescence, and the stomach is transected along the proximal fluorescent edge to remove the tumor.
A minimum of 3-year follow-up was achieved.

Randomization:
1. Eligibility & Enrollment
Eligible participants meeting inclusion/exclusion criteria will be assigned unique Study IDs (001-410). Due to the open-label nature, participants will be informed about group allocation post-randomization
2. Randomization Setup
Allocation ratio: 1:1 (205 in ICG Group vs 205 in Control Group)
Method: Computer-generated simple randomization sequence using R statistical software (sample() function)
Validation: Sequence will be verified by independent biostatistician
3. Implementation
System: Interactive Web Response System (IWRS) with real-time allocation
Timing: Performed immediately after completion of baseline assessments
Notification: Instant electronic notification to site investigators; Participants receive allocation information during the same visit
4. Quality Control
Audit Trail: Complete timestamped randomization records maintained
Balance Monitoring: Weekly checks of allocation ratios
5. Documentation
CRF will prominently display "OPEN-LABEL STUDY" header
All randomization documents archived as "UNBLINDED MATERIALS"
Protocol will state: "Due to the nature of interventions, this study employs an open-label design"

Intervention Type
Procedure/Surgery

Primary outcome(s)
Positive rate of initial proximal margin is measured by intraoperative frozen section examination.

Key secondary outcome(s)
1. Incidence of intraoperative extended resection is measured using operative records at the time of surgery
2. Length of proximal margin is measured using a surgical ruler on the resected specimen immediately after resection
3. Morbidity rate is measured using Clavien-Dindo classification based on clinical records during the postoperative hospital stay and follow-up at 3 years
4. Mortality rate is measured using clinical records and death certificates during the postoperative period up to 3 years
5. 3-year overall survival rate is measured using patient follow-up data and survival status at 3 years post-surgery
6. 3-year disease-free survival rate is measured using follow-up imaging (CT or PET-CT), endoscopy, and tumor marker assessment at regular intervals up to 3 years post-surgery
7. 3-year recurrence pattern is measured using imaging (CT or PET-CT), endoscopy, and tumor marker assessment at regular intervals up to 3 years post-surgery
8. Number of dissected lymph nodes is measured using histopathological examination of surgical specimens immediately after surgery
9. Number of positive lymph nodes is measured using histopathological examination of surgical specimens immediately after surgery
10. Operation time is measured using operative records at the time of surgery
11. Intraoperative blood loss is measured using anesthetic and surgical records at the time of surgery
12. Postoperative recovery course is measured using clinical records including time to first flatus, time to oral intake, and length of hospital stay during the postoperative period
13. Positive rate of gastric tissue at 1cm from the tumor (GT1) is measured using histopathological examination of resected specimens immediately after surgery
14. Positive rate of gastric tissue at 2cm from the tumor (GT2) is measured using histopathological examination of resected specimens immediately after surgery
15. Positive rate of gastric tissue at 3cm from the tumor (GT3) is measured using histopathological examination of resected specimens immediately after surgery
16. Positive rate of gastric tissue at 4cm from the tumor (GT4) is measured using histopathological examination of resected specimens immediately after surgery

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Aged 18-75 years.
2. Pathologically proven gastric adenocarcinoma.
3. Clinical stage T1-4a, N0/+, M0 according to the 8th edition of American Joint Committee on Cancer (AJCC) TNM classification.
4. Scheduled for distal gastrectomy with D2 lymphadenectomy, and possible for R0 surgery by this procedure.

5. Performance status of 0 or 1 on Eastern Cooperative Oncology Group scale (ECOG).
6. American Society of Anesthesiology score (ASA) class I, II, or III.
7. Written informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
422

Key exclusion criteria
1. Allergic to iodine or specific contrast agents.
2. History of previous upper abdominal surgery.
3. History of previous gastrectomy, endoscopic mucosal resection or endoscopic submucosal dissection.
4. History of previous neoadjuvant chemotherapy or radiotherapy.
5. Suffering from other serious diseases, including cardiovascular, respiratory, kidney, or liver disease, complicated by poorly controlled hypertension, diabetes, mental disorders or disease.
6. Need for combined organ resection.
7. Need for concurrent surgeries due to other surgical diseases.
8. Direct invasion of pancreas, spleen or other organs nearby in the preoperative examinations.

Date of first enrolment
07/09/2019

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
China

Study participating centre

Qilu Hospital of Shandong University
107 Wenhuaxi Road
Jinan
China
250012

Sponsor information

Organisation
Qilu Hospital of Shandong University

ROR
https://ror.org/056ef9489

Funder(s)

Funder type
University/education

Funder Name
Shandong University

Alternative Name(s)
SDU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The dataset analyzed during the current study will be available upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/01/2026	23/01/2026	Yes	No