

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
10/06/2025	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
12/06/2025	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
23/01/2026	Surgery	

## 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 Wenhuxi Road

Jinan

China

250012

+86 18560085155

wenbin\_yu2003@163.com

**Type(s)**

Public

**Contact name**

Dr Yize Liang

**Contact details**

107 Wenhuxi Road

Jinan

China

250012

+86 17660440802

liangyize1@163.com

**Type(s)**

Scientific

**Contact name**

Prof Zhibo Yan

**Contact details**

107 Wenhuxi Road

Jinan

China

250012

+86 18560085166

zhiboyan@sdu.edu.cn

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## 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 Wenhuxi Road, Jinan, 250012, China; +86-531-82169166; qlyykyc@163.com), ref: 2019085

### Study design

Single-center interventional open-label randomized controlled trial

### Primary study design

Interventional

### 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 Wenhuxi 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?
<a href="#"><u>Results article</u></a>		05/01/2026	23/01/2026	Yes	No