

# Late intestinal complications in minimally invasive total gastrectomy for gastric cancer

<b>Submission date</b> 28/02/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/03/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/09/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Although minimally invasive total gastrectomy for gastric cancer is commonly performed, reports regarding late complications are limited. Since 2009, the study team made several improvements each time severe late complications were experienced. This study aims to evaluate the clinical efficacy of these improved procedures in preventing late complications.

### Who can participate?

Patients who underwent laparoscopic or robotic total gastrectomy for gastric cancer between January 2009 and December 2019

### What does the study involve?

The patients will be divided into two groups: Period-I (2009–2013, before established standardization of procedure) and Period-II (2014–2019, after established standardization of procedure). The procedure has been standardized through four major steps, typified by the closure of the mesentery and diaphragm crus, and fixation and linearization around the anastomotic site of esophagojejunostomy. The incidence of late complications will be retrospectively compared between the two groups.

### What are the possible benefits and risks of participating?

There were no direct benefits for participating, but possibility to contribute to future advances in medical science. There were no risks of participating, due to no interventions required.

### Where is the study run from?

Fujita Health University

### When is the study starting and how long is it expected to run for?

August 2020 to August 2023

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Susumu Shibasaki, susumushi48@mist.ocn.ne.jp

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Susumu Shibasaki

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

The risk factor of late intestinal complications in minimally invasive total gastrectomy for gastric cancer

### Study objectives

The standardized procedures will prevent late intestinal complications by comparing two periods: before and after the establishment of standardization of the minimally invasive total gastrectomy procedure.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 29/08/2020, The Institutional Review Board of Fujita Health University (1-98, Dengakugakubo, Kutsukake, Toyoake, 470-1192, Japan; +81-562-93-2865; f-irb@fujita-hu.ac.jp), ref: HM23-318

## **Study design**

Single-center retrospective cohort study

## **Primary study design**

Observational

## **Study type(s)**

Prevention, Treatment

## **Health condition(s) or problem(s) studied**

Prevention of late intestinal complications in patients who underwent minimally invasive total gastrectomy for gastric cancer.

## **Interventions**

The procedure comprises four major steps, typified by the closure of the mesentery and diaphragm crus, and fixation and linearization around the anastomotic site of esophagojejunostomy.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

The incidence of complications within 3 years after surgery measured using data collected from medical records at one time point

## **Key secondary outcome(s)**

The following secondary outcome variables will be measured using data collected from medical records at one time point:

1. Clinicopathological characteristics
2. Short-term surgical outcomes:
  - 2.1. Operative time
  - 2.2. Surgeon console time
  - 2.3. Estimated blood loss
  - 2.4. Number of dissected lymph nodes
  - 2.5. Rates of local and systemic complications
  - 2.6. Mortality rate
  - 2.7. Length of postoperative hospitalization
  - 2.8. Severity of reflux esophagitis at preoperative year (POY) 1
  - 2.9. Body weight loss rate at POY 1
3. Long-term survival outcomes:
  - 3.1. 3-year overall survival (OS)
  - 3.2. 3-year relapse-free survival (RFS)

## **Completion date**

31/08/2023

# Eligibility

## Key inclusion criteria

1. Patients between January 2009 and December 2019.
2. Patients underwent total gastrectomy for gastric cancer at our division.

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Mixed

## Lower age limit

20 years

## Upper age limit

91 years

## Sex

All

## Total final enrolment

302

## Key exclusion criteria

1. Open gastrectomy
2. Clinical or pathological stage IV
3. Remnant gastric cancer
4. Palliative surgery
5. EGJ cancer
6. Observation period < 90 days
7. Use of circular stapler

## Date of first enrolment

01/01/2021

## Date of final enrolment

31/12/2022

# Locations

## Countries of recruitment

Japan

## Study participating centre

**Fujita Health University**  
Dengakugakubo, Kutsukake  
Toyoake  
Japan  
470-1192

## Sponsor information

### Organisation

Fujita Health University

### ROR

<https://ror.org/046f6cx68>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Susumu Shibasaki, [susumu.shibasaki@fujita-hu.ac.jp](mailto:susumu.shibasaki@fujita-hu.ac.jp). The data that support the findings of this study will be shared. All data were anonymized so consent from participants was not required or obtained.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Participant information sheet	04/06/2024	09/09/2024	Yes	No
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes