

# 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

### **Study website**

[https://fujita.bvits.com/esct/publish\\_document.aspx?ID=3570](https://fujita.bvits.com/esct/publish_document.aspx?ID=3570)

## **Contact information**

### **Type(s)**

Public, Scientific, Principal Investigator

### **Contact name**

Dr Susumu Shibasaki

### **ORCID ID**

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### **Contact details**

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

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

**Secondary study design**

Cohort study

**Study setting(s)**

Medical and other records

**Study type(s)**

Prevention, Treatment

**Participant information sheet**

No participant information sheet available

**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 measure**

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

**Secondary outcome measures**

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)

**Overall study start date**

01/01/2020

**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

**Age group**

Mixed

**Lower age limit**

20 Years

**Upper age limit**

91 Years

**Sex**

Both

**Target number of participants**

302

**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

**Sponsor details**

Center for Clinical Trial and Research Support, 1-98, Dengakugakubo, Kutsukake

Toyoake

Japan

Aichi 470-1192

+81-562-93-2884

c-int-rl@fujita-hu.ac.jp

**Sponsor type**

University/education

**Website**

<https://www.fujita-hu.ac.jp/>

**ROR**

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

# Funder(s)

Funder type  
Other

Funder Name  
Investigator initiated and funded

## Results and Publications

Publication and dissemination plan  
Planned publication in a high-impact peer-reviewed journal

Intention to publish date  
31/12/2024

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. 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>		04/06/2024	09/09/2024	Yes	No