

# Comparison of laparoscopic versus open radical gastrectomy for advanced gastric cancer

<b>Submission date</b> 22/01/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/03/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/04/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT01043835

## Study information

**Scientific Title**  
Comparison of laparoscopic versus open radical gastrectomy for advanced gastric cancer: a prospective randomised controlled trial

**Study objectives**

The use of laparoscopic surgery in the management of advanced gastric cancer (AGC) has not yet met with widespread acceptance and remains limited to only a few centres. The purpose of this study is to compare the short- and long-term results between the laparoscopy-assisted gastrectomy and the open gastrectomy.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics Committee of Southwest Hospital, Third Military Medical University, approved on the 24th September 2009 (ref: KY200908)

### **Study design**

Prospective randomised trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Advanced gastric cancer

### **Interventions**

Laparoscopy-assisted gastrectomy:

One initial 10-mm trocar for a laparoscope was inserted below the umbilicus. Another 10-mm trocar was introduced in the left preaxillary line 2 cm below the costal margin as a major hand port. A 5-mm trocar then was inserted in the left midclavicular line 2 cm above the umbilicus as an accessory port, and a 15-mm trocar (also as an accessory port) was placed at the contralateral site, through which a linear cutter was inserted. A 5-mm trocar was inserted in the right preaxillary line 2 cm below the costal margin for traction and exposure of the liver. The operator stood on the left side of the patient. Subtotal or total gastrectomy and D2 lymph node dissection will be performed basically. As a general rule, Billroth I, Billroth II or Roux-Y method was used for gastric reconstruction for all cases. Dissected stomach and lymph node are collected through additional 3 - 5 cm incision at a median superior abdominal incision.

Open gastrectomy:

Approximately 15 - 20 cm length incision is made from falciform process to periumbilical area. Subtotal or total gastrectomy and D2 lymph node dissection will be performed basically. As a general rule, Billroth I, Billroth II or Roux-Y method was used for gastric reconstruction for all cases.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Disease free survival at 3 years

**Key secondary outcome(s)**

Complications, recurrence, quality of life measured by EORTC QLQ-C30 V 3.0 and EORTC QLQ-STO22 at 3 years

**Completion date**

31/01/2015

**Eligibility**

**Key inclusion criteria**

1. Pathologically proven gastric adenocarcinoma
2. Aged older than 18 years old, younger than 80 years old, either sex
3. Pre-operative stage (computed tomography [CT], gastrofiberscopy [GFS] stage): cT2N0M0, cT2N1M0, cT2N2M0, cT3N0M0, cT3N1M0, cT3N2M0
4. American Society of Anaesthesiologists (ASA) score: less than or equal to 3
5. No invasion of the gastric serosa exceeding 10 cm<sup>2</sup> according to ultrasound examination or examination during surgery
6. No history of other cancer
7. No history of chemotherapy or radiotherapy
8. Written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Concurrent cancer patients or patient who was treated due to other types of cancer before the patient was diagnosed as a gastric cancer patient
2. Patient who was treated by other types of treatment methods, such as chemotherapy, immunotherapy, or radiotherapy
3. Patient who was received upper abdominal surgery (except laparoscopic cholecystectomy)
4. ASA score: greater than 3
5. Contraindication of laparoscopy: severe cardiac disease, abdominal wall hernias, diaphragmatic hernias, uncorrected coagulopathies, portal hypertension, pregnancy
6. Complicated case needed to get emergency operation
7. Any accompanying surgical condition needed to be performed in same time

**Date of first enrolment**

01/02/2010

**Date of final enrolment**

31/01/2015

## Locations

**Countries of recruitment**

China

**Study participating centre**

Department of General Surgery and Center of Microinvasive Gastrointestinal Surgery

Chongqing

China

400038

## Sponsor information

**Organisation**

Southwest Hospital (China)

**ROR**

<https://ror.org/02jn36537>

## Funder(s)

**Funder type**

Government

**Funder Name**

Chongqing Municipal Government (China) - Science and Technology Research

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2018	11/04/2019	Yes	No
<a href="#">Results article</a>	results	01/06/2019	11/04/2019	Yes	No