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Comparison of laparoscopic versus open radical gastrectomy for advanced gastric cancer

Submission date 22/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/03/2010	**Overall study status** Completed	
Last Edited 11/04/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01043835

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Disease free survival at 3 years

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

Overall study start date
01/02/2010

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^2 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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
328

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)

Sponsor details
c/o Yu Pei Wu, Ph. D
Department of General Surgery and Center of Microinvasive Gastrointestinal Surgery

Chongqing
China
400038

Sponsor type
Hospital/treatment centre

Website
http://english.swhospital.com/default.aspx

ROR
https://ror.org/02jn36537

Funder(s)

Funder type
Government

Funder Name
Chongqing Municipal Government (China) - Science and Technology Research

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/05/2018	11/04/2019	Yes	No
Results article	results	01/06/2019	11/04/2019	Yes	No