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Laparoscopic endoscopic cooperative surgery for the duodenal neuroendocrine tumor

Submission date
10/04/2023

Recruitment status
Recruiting

Registration date
15/04/2023

Overall study status
Ongoing

Last Edited
12/04/2023

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Duodenal neuroendocrine tumors (D-NETs) are uncommon tumors that start in the nerves and gland cells of the first part of the small intestine. Laparoscopic and endoscopic cooperative surgery (LECS) is a promising approach for treating gastrointestinal (digestive system) tumors. This study aims to evaluate the feasibility and safety of LECS for D-NETs.

Who can participate?
Patients aged 20-80 years with duodenal neuroendocrine tumors

What does the study involve?
Patients with D-NET who had LECS have their medical records retrospectively evaluated. A CT scan and upper gastrointestinal endoscopy with biopsy are required for routine evaluation of the disease and detection of probable metastases (secondary tumors). After the initial diagnosis, endoscopic ultrasonography (EUS) is used to evaluate the invasive depth and exclude local lymph node metastases. Functional imaging, like somatostatin receptor scintigraphy, is used when there is an abnormality in conventional imaging.
Generally, LECS is performed through collaboration between the surgical team and endoscopists. The same skilled endoscopist (Dr Gui-Qi Wang) performs all endoscopic procedures with endoscopic full-thickness resection.

What are the possible benefits and risks of participating?
The benefits and risks are the same as the usual surgery

Where is the study run from?
National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College (China)

When is the study starting and how long is it expected to run for?
September 2018 to January 2027

Who is funding the study?
1. Sanming Project of Medicine in Shenzhen (China)
2. Chinese Academy of Medical Sciences (China)

Who is the main contact?
Dr Hoi-Ioi Ng, 15811329134@139.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Hoi-Ioi Ng

Contact details
National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital
Chinese Academy of Medical Sciences and Peking Union Medical College
Beijing
China
100021
+86 (0)15811329134
15811329134@139.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Laparoscopic endoscopic cooperative surgery for the duodenal neuroendocrine tumor

Study objectives
Laparoscopic and endoscopic cooperative surgery (LECS) is feasible for duodenal neuroendocrine tumor (D-NET)

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 03/11/2021, National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, National GCP Center for Anticancer Drugs, The Independent Ethics Committee (No.17 Panjiayuan Nanli, Chaoyang District, Beijing, 100021, China; +86 (0)8778 8495; cancergcp@163.com), ref: 21-458/3129

Study design
Non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Duodenal neuroendocrine tumor

Interventions
Patients with D-NET who had LECS had their medical records retrospectively evaluated. Enhanced computed tomography (CT) scan and upper gastrointestinal (GI) endoscopy with biopsy were required for routine evaluation of the disease and detection of probable metastases. After the initial diagnosis, endoscopic ultrasonography (EUS) was indicated to evaluate the invasive depth and exclude local lymph node metastasis (LNM). Functional imaging, like somatostatin receptor scintigraphy (for example, positron emission tomography (PET)/CT with 68Ga-DOTA-peptides), would be indicated when there is an abnormal in conventional imaging. The LECS criteria included the following: 1) Histological confirmation of NETs; 2) tumor diameter no greater than 10 mm; 3) confined to the mucosal or submucosal layer on EUS; 4) absence of regional or distant lymph node metastases on imaging; 5) non-ampullary NETs.

Endoscopic procedure
Generally, LECS was performed through collaboration between the surgical team and endoscopists. The same skilled endoscopist (Dr Gui-Qi Wang) performed all endoscopic procedures with endoscopic full-thickness resection (EFTR). The details of EFTR have been discussed in previous research.

Surgical procedure
The patient was positioned with legs apart in a modified Trendelenburg position. Five trocars were put in a V shape. As an observation port, a 10-mm trocar was placed through the umbilical cord. The pneumoperitoneum was created by the insufflation of carbon dioxide to an abdominal pressure of 12 mmHg. Trocars measuring 5 mm were inserted into the upper right, upper left, and left abdominal lateral regions, respectively. As the main port, a 12-mm trocar was placed in the right lateral abdominal region. Kocher mobilization was undertaken, if necessary, to expose the second portion of the duodenum. This procedure made it easier to have a clear visualization for suturing. The lesion was collected in a plastic bag and extracted through the main port. The defect was manually closed using a 15-cm barbed running suture (V-LOCTM 180 Absorbable Wound Closure Device, Covidien, Mansfield, MA). Under the surveillance of the surgeon and endoscopist, the absence of air leakage and stenosis was finally confirmed. A drainage catheter was positioned near the duodenal incision. A feeding tube was usually inserted through the closed wound in case of duodenal stasis. On the third postoperative day, duodenal patency was evaluated by upper gastrointestinal imaging.

Intervention Type
Procedure/Surgery

Primary outcome(s)
En bloc resection rate measured using pathology at 1 month after surgery

Key secondary outcome(s))
1. Absence of involvement of the lateral or vertical margins measured using pathology at 1 month after surgery
2. Absence of lymphovascular invasion measured using pathology at 1 month after surgery

Completion date
01/01/2027

Eligibility

Key inclusion criteria
1. Biopsy showed NET in the duodenum
2. Aged 20-80 years old
3. Agree to have LECS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
Lost to follow-up

Date of first enrolment
07/09/2018

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
China

Study participating centre
National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing 100021, China
PanJiaYuanNanLi 17#
Beijing
China
100021

Sponsor information

Organisation
Chinese Academy of Medical Sciences & Peking Union Medical College

ROR
https://ror.org/02drdmm93

Funder(s)

Funder type
University/education

Funder Name
Chinese Academy of Medical Sciences

Alternative Name(s)
CAMS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name

Sanming Project of Medicine in Shenzhen

Alternative Name(s)
'sanming' project of medicine in Shenzhen, Sanming Project of Medicine in Shenzhen, San-Ming Project of Medicine in Shenzhen, Sanming Project of Medicine in Shenzen Municipal

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated and analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication