

# Laparoscopic endoscopic cooperative surgery for the duodenal neuroendocrine tumor

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 15/04/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 12/04/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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-loi Ng, 15811329134@139.com

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Hoi-loi Ng

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

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](mailto: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#  
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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 Shenzhen 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