

Laparoscopic endoscopic cooperative surgery for the duodenal neuroendocrine tumor

Submission date 10/04/2023	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/04/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/04/2023	Condition category 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

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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

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

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

En bloc resection rate measured using pathology at 1 month after surgery

Secondary outcome measures

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

Overall study start date

01/09/2018

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

Age group

Adult

Lower age limit

20 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

30

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

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Sponsor information**Organisation**

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Sponsor type

University/education

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ROR

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/09/2027

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