

# Comparing imaging scans and tumor tissue analysis for assessing treatment response in pancreatic cancer patients receiving chemotherapy before surgery

<b>Submission date</b> 07/10/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/10/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/10/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Pancreatic cancer patients often receive chemotherapy before surgery to shrink tumors. Doctors use CT scans and blood tests to assess the effectiveness of the treatment before surgery. After surgery, pathologists examine the removed tumor tissue to determine the actual treatment response, called the tumor regression grade (TRG). However, it is unclear how well the pre-surgery assessments predict the actual tumor response found in the tissue.

This study aims to compare pre-surgery assessments (CT scans, CA19-9 blood marker, tumor stage changes) with the actual tumor response seen under the microscope. We will examine whether these pre-surgery tests reliably predict treatment response and survival outcomes. The findings will help doctors make more informed decisions about surgery timing and postoperative treatment intensity.

### Who can participate?

Adults over 18 years old with pancreatic cancer who received chemotherapy before surgery at National Cheng Kung University Hospital between 2009 and 2023.

### What does the study involve?

This study reviews existing medical records only - no additional tests or treatments are required. The research team will collect information from participants' records, including:

1. CT scans and blood tests before and after chemotherapy
2. Tumor examination results after surgery
3. Surgery details and complications
4. Cancer recurrence and survival data

We analyze whether pre-surgery assessments accurately predicted the actual tumor response and identify factors associated with better survival.

### What are the possible benefits and risks of participating?

Benefits: There is no immediate benefit to participants; however, the results may help future

patients by enhancing doctors' ability to interpret tests during treatment and make more informed decisions about surgery timing and postoperative treatment.

Risks: None. This is a medical records review only. All data will be anonymized and kept strictly confidential.

Where was the study conducted?

National Cheng Kung University Hospital (Taiwan)

When was the study conducted?

April 2024 to October 2025

Who funded the study?

Clinical Research Center of National Cheng Kung University Hospital (Taiwan)

Who is the main contact?

Dr Ting-Kai Liao, n049550@mail.hosp.ncku.edu.tw

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Ting-Kai Liao

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

DISCORD-PDAC

## Study information

### Scientific Title

Discordance between pathological tumor regression grade and clinical response assessment methods in pancreatic ductal adenocarcinoma after neoadjuvant chemotherapy: implications for treatment decision-making

**Acronym**

DISCORD-PDAC

**Study objectives**

1. Evaluate the prognostic value of pathological tumor regression grade (TRG) across different disease stages and resectability categories
2. Systematically assess the concordance between pathological TRG and multiple clinical response assessment methods.

**Ethics approval required**

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**Ethics approval(s)**

approved 02/05/2024, Institution Review Board, National Cheng Kung University Hospital (No. 138, Sheng-Li Road, Tainan, 704, Taiwan; +886 (0)6 235 3535; em73635@mail.hosp.ncku.edu.tw), ref: A-ER-113-127

**Study design**

Single-center retrospective observational study

**Primary study design**

Observational

**Study type(s)**

Treatment

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

Pancreatic cancer

**Interventions**

The participants were patients of pancreatic cancer who received neoadjuvant chemotherapy then surgical resection. Survival outcomes were analyzed comparing pathological tumor regression grades.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Overall survival was measured using the Kaplan-Meier method and Cox regression model at the time of death or last follow-up

**Key secondary outcome(s)**

1. Progression-free survival was measured using the Kaplan-Meier method and Cox regression model at the time of disease recurrence or last follow-up
2. Tumor regression grade was measured using CAP protocols at the pathological exam of the surgical specimens

**Completion date**

30/10/2025

# Eligibility

## Key inclusion criteria

1. Histologically confirmed pancreatic ductal adenocarcinoma (PDAC)
2. Completion of at least four cycles of neoadjuvant chemotherapy (NAC)
3. Surgical resection with curative intent
4. Available pathological TRG assessment
5. Complete clinical and follow-up data

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

90 years

## Sex

All

## Total final enrolment

281

## Key exclusion criteria

1. Other subtypes of pancreatic cancer
2. Palliative surgery
3. Incomplete pathological assessment

## Date of first enrolment

01/01/2009

## Date of final enrolment

31/12/2023

# Locations

## Countries of recruitment

Taiwan

## Study participating centre

**National Cheng Kung University Hospital**  
No. 138, Sheng-Li Road  
Tainan  
Taiwan  
704

## Sponsor information

### Organisation

Clinical Research Center of National Cheng Kung University Hospital

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Clinical Research Center of National Cheng Kung University Hospital

## Results and Publications

### Individual participant data (IPD) sharing plan

The dataset generated during and/or analysed during the current study will be available from the corresponding author upon reasonable request.

Contact for data access: Ting-Kai Liao, n049550@mail.hosp.ncku.edu.tw

Type of data to be shared: De-identified individual participant data including demographics, clinical characteristics, imaging results, pathological findings, and treatment outcomes

Date of availability: Data will be available from 6-12 months after primary publication to 5 years after publication upon reasonable request

Consent for data sharing: Consent for data sharing was not specifically obtained from participants as this is a retrospective study using existing medical records. However, the study was approved by the IRB with a waiver of informed consent for this retrospective analysis.

Data anonymization: All data will be fully de-identified. All direct identifiers will be removed prior to sharing.

Ethical/legal restrictions: Data sharing requests will be reviewed on a case-by-case basis and must include a methodologically sound proposal with clearly defined research aims. A data sharing agreement will be required.

Additional comments: Data access requests should include a brief research proposal outlining the intended use of the data. Requests will be responded to within 30 days.

### IPD sharing plan summary

Available on request

