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

Submission date
07/10/2025

Recruitment status
No longer recruiting

Registration date
09/10/2025

Overall study status
Completed

Last Edited
08/10/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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
Ethics approval required

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
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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