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Using chemotherapy and immune therapy before endoscopic surgery for esophageal cancer

Submission date 26/01/2025	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/02/2025	**Overall study status** Ongoing	
Last Edited 05/02/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
In patients with advanced esophageal squamous cell carcinoma (ESCC), the combination of chemotherapy and immunotherapy has been shown to result in pathological complete response rates of approximately 32.4%. This study aims to evaluate the efficacy and safety of neoadjuvant chemotherapy combined with immunotherapy followed by sequential endoscopic resection for patients with cT1bN0M0 ESCC.

Who can participate?
Patients aged over 18 years and under 75 years of age diagnosed with T1b stage ESCC and have no clear lymph node or distant metastasis detected by imaging examinations

What does the study involve?
The treatment regimen consists of three cycles of concurrent neoadjuvant chemotherapy and two cycles of immunotherapy. A post-treatment endoscopic assessment will be conducted within four weeks of the conclusion of neoadjuvant therapy. If the primary lesions showed a significant size reduction, the patient underwent endoscopic resection. The primary study endpoints are the safety and the rate of pathological complete response.

What are the possible benefits and risks of participating?
The greatest benefit for patients is through this study, which avoids undergoing surgical procedures and preserves the integrity of the esophageal organs. The main risk of the research is the complications caused by chemotherapy and immunotherapy.

Where is the study run from?
The Cancer Hospital of the Chinese Academy of Medical Sciences, China

When is the study starting and how long is it expected to run for?
September 2023 to December 2026

Who is funding the study?
The Cancer Hospital of the Chinese Academy of Medical Sciences, China

Who is the main contact?
Dr Lizhou Dou, ddx198707@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Efficacy and safety of neoadjuvant chemotherapy combined with immunotherapy followed by sequential endoscopic resection for cT1bNOMO esophageal cancer

Study objectives
This study evaluates the efficacy and safety of neoadjuvant chemotherapy combined with immunotherapy followed by endoscopic resection in patients with cT1bN0M0 esophageal cancer. This treatment regimen is an effective non-surgical option for patients with early-stage esophageal cancer, with the potential to improve their prognosis and quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 14/09/2023, Independent Ethics Committee of the National Cancer Center/ Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College/National GCP Center for Anticancer Drugs (Panjiayuannanli No 17, Chaoyang District, Beijing, 100021, China; +86 010-87788495; cancergcp@163.com), ref: 23/388-4130

Study design
Single-center interventional non-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
The objective of this study is to evaluate the efficacy and safety of neoadjuvant chemotherapy combined with immunotherapy followed by sequential endoscopic resection in patients with cT1bN0M0 esophageal cancer

Interventions
Patients with cT1bN0M0 esophageal cancer who meet the inclusion and exclusion criteria will receive 3 cycles of concurrent neoadjuvant chemotherapy (an albumin-bound intravenous infusion of paclitaxel 150 mg/m2 and an intravenous infusion of cisplatin 50 mg/m2 on day 1, and then every 2 weeks thereafter) and 2 cycles of immunotherapy (intravenous injection of panolizumab 200 mg on day 1 and then every 3 weeks thereafter) within 4 weeks of completing neoadjuvant therapy, followed by endoscopic evaluation. If the main lesions show a significant reduction from the pretreatment size, patients will undergo endoscopic resection within 6 weeks after completion of neoadjuvant therapy.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pathological complete response (pCR) measured using histopathological specimens after endoscopic resection

Key secondary outcome(s))
1. Disease-free survival (DFS), defined as the time from resection to recurrence of tumor or death, measured using data collected in medical records at one time point
2. Overall survival (OS), defined as the time from study inclusion to death, measured using data collected in medical records at one time point

Completion date
31/12/2031

Eligibility

Key inclusion criteria

1. Age ≥18 years, ≤75 years
2. Diagnosis of esophageal squamous cell carcinoma confirmed by biopsy according to at least one of the following criteria:
2.1. Lesion infiltration into the submucosa, as determined by combined gastroscopy and endoscopic ultrasound
2.2. No obvious lymph node metastasis or distant metastasis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Esophageal adenocarcinoma and precancerous lesions
2. Current antiplatelet, anticoagulant, or thrombolytic therapy (such as with warfarin, heparin, clopidogrel, aspirin, streptokinase, and urokinase)
3. Myocardial infarction or other severe heart diseases in the past 6 months
4. Serious cerebrovascular diseases, such as cerebral hemorrhage and cerebral infarction, in the past 6 months
5. Previous surgery or chemotherapy and immunotherapy other than radiofrequency therapy, cryotherapy, photodynamic therapy, or ER due to esophageal tumors
6. Unmanaged mental illness and/or known drug or alcohol dependence that has not been cured, which limits the ability to understand or follow the instructions related to informed consent, post-treatment instructions or follow-up guidelines
7. Incomplete clinical data (ambiguous diagnosis, incomplete medical history, incomplete medication records, etc.)
8. Regional lymph node metastasis confirmed by imaging examination and needle biopsy
9. Signs of eosinophilic esophagitis found on endoscopic examination and/or histological examination
10. Grade C or D active reflux esophagitis
11. Allergy to platinum or paclitaxel
12. Pregnancy/lactation
13. Inability to provide signed informed consent

Date of first enrolment
20/09/2023

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
China

Study participating centre
National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College
Panjiayuannanli No 17, Chaoyang District, Beijing ,China
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Sponsor information

Organisation
Chinese Academy of Medical Sciences & Peking Union Medical College

ROR
https://ror.org/02drdmm93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cancer Institute and Hospital, Chinese Academy of Medical Sciences

Alternative Name(s)
Cancer Institute and Hospital

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed in the current study be stored in a non-publicly available repository at the patient data records of the Cancer Hospital of the Chinese Academy of Medical Sciences

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			05/02/2025	No	No