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Analysis of comfort and safety with versus without nasogastric tube following endoscopic resection of early esophageal cancers and precancerous lesions

Submission date
09/09/2025

Recruitment status
No longer recruiting

Registration date
11/09/2025

Overall study status
Completed

Last Edited
21/10/2026

Condition category
Cancer

[X] 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
Endoscopic resection (ER) is a common treatment for early esophageal cancer and precancerous lesions. However, whether placing a nasogastric tube (NGT) after ER is beneficial remains unclear. This study aims to compare the safety and comfort of patients with versus without NGT placement after ER.

Who can participate?
Adults with early esophageal cancer or precancerous lesions confirmed by pathology, suitable for endoscopic treatment, without esophageal stricture, and with lesions involving ≤75% of the esophageal circumference.

What does the study involve?
Participants will be randomly assigned to either have a nasogastric tube placed for 48 hours after ER or not have one placed. Comfort and safety outcomes will be assessed through questionnaires and clinical evaluations.

What are the possible benefits and risks of participating?
Benefits may include improved comfort and shorter hospital stays. Risks are minimal but may include discomfort from the tube or routine procedural complications.

Where is the study run from?
The study is conducted at multiple centers in China, led by the National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences.

When is the study starting and how long is it expected to run for?
September 2025 to March 2026

Who is funding the study?
1. Chinese Academy of Medical Sciences (CAMS) Innovation Fund for Medical Science (CIFMS)
2. National High Level Hospital Clinical Research Fund and National Cancer Center Climbing Fund
3. Non-profit Central Research Institute Fund of Chinese Academy of Medical Sciences.

Who is the main contact?
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National High Level Hospital Clinical Research Funding and National Cancer Center Climbing Fund
NCC202418001

National High Level Hospital Clinical Research Funding and National Cancer Center Climbing Fund
NCC202418005

Study information

Scientific Title
Analysis of comfort and safety with versus without nasogastric tube following endoscopic resection of early esophageal cancers and precancerous lesions: a prospective, multicenter, randomized controlled study

Study objectives
Current study objectives as of 16/10/2026:
The primary non-inferiority hypothesis concerned delayed bleeding. Subsequent secondary endoscopic intervention was recorded as a primary safety endpoint and interpreted descriptively, because its occurrence could be influenced by the allocated postoperative management strategy.Furthermore, the study hypothesized that avoiding NGT placement would significantly improve patient comfort by reducing procedure-related discomfort and pain, and would avoid the unnecessary consumption of medical and nursing resources, thereby aligning with the principles of enhanced recovery after surgery (ERAS).

Previous study objectives:
The principal objectives of this study were to evaluate the necessity of nasogastric tube (NGT) placement following esophageal endoscopic resection (ER). The primary hypothesis was that withholding NGT placement would not increase the rate of secondary endoscopic intervention due to delayed bleeding, demonstrating non-inferiority in safety compared to routine NGT use. Furthermore, the study hypothesized that avoiding NGT placement would significantly improve patient comfort by reducing procedure-related discomfort and pain, and would avoid the unnecessary consumption of medical and nursing resources, thereby aligning with the principles of enhanced recovery after surgery (ERAS).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/04/2022, 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 ((17 Panjiayuan Nanli, Chaoyang District, Beijing, 100021, China; +8610-87788495; cancergcp@163.com), ref: 22/163-3364

Primary study design
Interventional

Study design
Multicenter interventional randomized controlled study

Study type(s)
Safety, Treatment

Health condition(s) or problem(s) studied
Postoperative management following endoscopic resection of early esophageal cancers and precancerous lesions

Interventions
Current interventions as of 20/10/2026:
This prospective, multicenter randomized controlled trial planned to enrol 204 participants. After endoscopic resection and confirmation of eligibility, total participants were randomly assigned (1:1) via a centralized system using R software to either the NGT-F group (no nasogastric tube placement) or the NGT-R group (nasogastric tube placement with external negative-pressure suction and drainage monitoring). The tube in the NGT-R group was removed 48 hours postoperatively.

Withdrawal/discontinuation criteria: Postoperative endotracheal-tube retention requiring inability to implement the allocated postoperative NGT strategy; such participants remain in the full analysis set and are excluded from the per-protocol analysis.

For patients receiving antithrombotic therapy, aspirin and clopidogrel were discontinued 7 days before ER and were generally resumed 7-14 days after ER. Rivaroxaban was discontinued 48 h before ER and was generally resumed 48 hours after the ER. The timing of postprocedural resumption was determined on an individual basis after comprehensive assessment of the depth of dissection, intraoperative bleeding and hemostasis, and the condition of the post-ER defect.

Previous interventions as of 16/10/2026:
This prospective, multicenter randomized controlled trial planned to enrol 204 participants. After endoscopic resection and confirmation of eligibility, total participants were randomly assigned (1:1) via a centralized system using R software to either the NGT-F group (no nasogastric tube placement) or the NGT-R group (nasogastric tube placement with external negative-pressure suction and drainage monitoring). The tube in the NGT-R group was removed 48 hours postoperatively.

Previous interventions:
This is a prospective, multicenter, randomized controlled trial. A total of 208 patients undergoing endoscopic resection for early esophageal cancer or precancerous lesions were randomly assigned (1:1) via a centralized system using R software to either the NO-NGTB group (no nasogastric tube placement) or the NGTB group (nasogastric tube placement with external negative pressure suction and drainage monitoring). The tube in the NGTB group was removed 48 hours postoperatively. The primary outcomes are the rate of secondary endoscopic intervention due to delayed bleeding and patient comfort scores (GCQ, subjective discomfort symptoms, VAS pain scores).

Intervention Type
Procedure/Surgery

Primary outcome(s)

Current primary outcomes as of 21/10/2026:
1. The incidence of delayed bleeding (between 24 hours and 30 days after the conclusion of ER) and subsequent secondary endoscopic intervention (between 24 hours and 30 days after the conclusion of ER), measured using clinical observation and endoscopic examination

Previous primary outcomes as of 16/10/2026:
1. The incidence of delayed bleeding and subsequent secondary endoscopic intervention measured using clinical observation and endoscopic examination within 30 days postoperatively

Previous primary outcomes:
1. The rate of secondary endoscopic intervention due to delayed bleeding (manifested as hematemesis/melena/hematochezia) measured using clinical observation and endoscopic examination within 30 days postoperatively
2. Patient comfort level measured using the Global Comfort Questionnaire (GCQ) and a Subjective Discomfort Symptom (SDS) record form at the time of surgery, 24 hours postoperatively, and 48 hours postoperatively
3. Throat and nasal pain measured using Visual Analogue Scale (VAS) pain scores when patients reported experiencing pain at the time of surgery, 24 hours postoperatively, or 48 hours postoperatively

Key secondary outcome(s)

Current key secondary outcomes as of 21/10/2026:
1. Postoperative pneumonia: the occurrence of postoperative pneumonia is assessed through inpatient monitoring and post-discharge telephone follow-up, with final ascertainment at 30 days after endoscopic resection (ER).
2. Delayed perforation: the occurrence of delayed perforation is assessed through inpatient monitoring and post-discharge telephone follow-up, with final ascertainment at 30 days after ER.
3. Postoperative nasogastric tube insertion: the occurrence of nasogastric tube insertion in the nasogastric tube-free group during the postoperative hospital stay is assessed using electronic medical records at hospital discharge.
4. Global comfort: global comfort is measured using the simplified Chinese version of the Global Comfort Questionnaire after ER on the day of the procedure and at 24 and 48 hours after ER. The arithmetic mean of the three total scores is calculated for each participant.
5. Subjective discomfort symptoms and symptom resolution: symptoms are assessed using an investigator-developed checklist after ER on the day of the procedure and at 24 and 48 hours after ER. Participants reporting symptoms are reassessed on postoperative days 3 and 7; resolution is defined as disappearance of the reported symptoms.
6. Throat and nasal pain intensity: pain intensity is measured using a visual analogue scale after ER on the day of the procedure and at 24 and 48 hours after ER in participants reporting the corresponding symptom of throat pain or nasal pain.
7. Unplanned nasogastric tube removal: the occurrence of unplanned nasogastric tube removal in the nasogastric tube-retention group during the postoperative hospital stay is assessed using electronic medical records at hospital discharge.

Previous key secondary outcomes as of 16/10/2026:
1. Patient comfort level measured using the Global Comfort Questionnaire (GCQ) and a Subjective Discomfort Symptom (SDS) record form at the time of surgery, 24 hours postoperatively, and 48 hours postoperatively
2. Throat and nasal pain measured using Visual Analogue Scale (VAS) pain scores when patients reported experiencing pain at the time of surgery, 24 hours postoperatively, or 48 hours

postoperatively
3. Remission of discomfort symptoms measured using patient report on postoperative days 3 and 7

Previous key secondary outcomes:
The rate of postoperative pneumonia, delayed postoperative perforation, reinsertion rate of nasogastric tubes in the NO-NGTB group, and spontaneous tube removal rate in the NGTB group were measured using clinical observation and endoscopic examination within 30 days postoperatively.

Completion date
15/03/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/10/2026:
1. A preoperative diagnosis of SEC or SEPL based on magnifying chromoendoscopy and biopsy, with contrast-enhanced CT excluding lymph node or distant metastasis
2. No pre-existing esophageal stricture and a lesion involving no more than 75% of the esophageal circumference on preoperative assessment
3. Suitability for ER
Postoperative histopathological confirmation of SEC or SEPL was also required. Eligibility for randomization was assessed using preoperative and intraoperative findings, whereas final histological confirmation was obtained after randomization.

Previous inclusion criteria:
1. All cases diagnosed preoperatively via electronic magnification chromoendoscopy and biopsy as early esophageal squamous cell carcinoma or precancerous lesions, with enhanced CT excluding lymph node or distant metastasis
2. No prior esophageal stricture, with preoperative assessment showing lesion circumference ≤75% of esophageal circumference
3. Postoperative pathology confirming early-stage esophageal squamous cell carcinoma or precancerous lesions
4. Eligibility for endoscopic treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
85 Years

Sex
All

Total final enrolment
211

Key exclusion criteria
Current key exclusion criteria as of 16/10/2026:
1. Intraoperative perforation occurring during ER before randomization.
2. Thrombocytopenia, coagulation disorder or bleeding tendency that could not be adequately corrected or managed before ER
3. Concomitant surgery on other sites such as hypopharynx or GI tract
4. Confirmed or possible pregnancy

Previous key exclusion criteria:
1. Successful ER, but intraoperative perforation occurred
2. Subjects currently receiving anticoagulant therapy (e.g., ongoing or recent use of warfarin, clopidogrel, heparin, aspirin, or other anticoagulants)

Date of first enrolment
25/09/2025

Date of final enrolment
11/02/2026

Locations

Countries of recruitment
China

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Sponsor information

Organisation
National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences, Peking Union Medical College

Funder(s)

Funder type
Research organisation

Funder Name
Chinese Academy of Medical Sciences (CAMS) Innovation Fund for Medical Science (CIFMS)

Funder Name
National Cancer Center Climbing Fund (NCC Climbing Fund)

Funder Name
National High Level Hospital Clinical Research Fund

Funder Name
Non-profit Central Research Institute Fund of Chinese Academy of Medical Sciences

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or 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