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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
11/09/2025

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
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?
October 2024 to October 2025. The study enrolment starts in September 2025 and is expected to run for one month.

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

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CAMS Innovation Fund for Medical Sciences (CIFMS) grant numbers 2021-I2M-1-061, 2021-I2M-1-015, 2021-I2M-1-013; National High Level Hospital Clinical Research Funding and National Cancer Center Climbing Fund grant number 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
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 14/11/2024, 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: 24/547-4827

Study design
Multicenter interventional randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment, Safety

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

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)
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))
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
20/10/2025

Eligibility

Key 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

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
09/09/2025

Date of final enrolment
09/10/2025

Locations

Countries of recruitment
China

Study participating centre
Department of Endoscopy, National Cancer Center/National Clinical Research Center for Cancer /Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College
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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

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