

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

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Registration date 11/09/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/09/2025	Condition category 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

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 $\leq 75\%$ 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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment, Safety

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

23/10/2024

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 \leq 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

Age group

Mixed

Lower age limit

18 Years

Upper age limit

85 Years

Sex

Both

Target number of participants

204

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

17, Panjiayuan Nanli, Chaoyang District

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Study participating centre

Center of Endoscopy, Cancer Hospital of Linzhou

Center of Endoscopy, Cancer Hospital of Linzhou

Linzhou, Henan
China
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Study participating centre

Center of Cancer Prevention and Treatment, Feicheng People's Hospital
Shandong
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271600

Study participating centre

Center of Endoscopy, Cixian Cancer Hospital
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056500

Study participating centre

Department of Gastroenterology, The Second Hospital of Hebei Medical University
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Hebei
China
05000

Sponsor information

Organisation

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

Sponsor details

Department of Endoscopy
Beijing
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Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/11/2025

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