

# Subserosal carbon nanoparticles for gastrectomy

<b>Submission date</b> 29/07/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/05/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Lymph node metastasis (tumour spreading into lymph nodes) is common in gastric (stomach) cancer. Extensive lymph node dissection is the fundamental step in radical gastrectomy (complete or near-complete removal of the stomach). Improving the visualization of lymph nodes can help surgeons identify and dissect lymph nodes during surgery. Carbon nanoparticles are an approved drug for visualization. However, it is unclear which approach of administration is best (subserosal injection or submucosal injection, i.e. injected under different layers of tissue). This study is designed to compare the effectiveness and safety of these two approaches in radical gastrectomy.

### Who can participate?

Patients between 18 and 75 years old with gastric cancer

### What does the study involve?

This study involves radical gastrectomy and the administration of carbon nanoparticles. Participants will be randomly allocated into two groups: Group 1: Subserosal injection of carbon nanoparticles for lymph node visualization. Group 2: Submucosal injection of carbon nanoparticles for lymph node visualization.

### What are the possible benefits and risks of participating?

Participants may benefit from an increased number of retrieved lymph nodes from the surgery, which will help with the precise staging of the tumour. Any risks related to the surgery itself (such as bleeding, obstruction, or anastomotic leakage) might occur during this study. There is a very limited risk of participating since this is a safe and approved drug for surgery.

### Where is the study run from?

Nanjing Drum Tower Hospital, the Affiliated Hospital of Nanjing University (China)

### When is the study starting and how long is it expected to run for?

September 2022 to December 2025

Who is funding the study?  
National Natural Science Foundation of China

Who is the main contact?  
Dr Song Liu, liusong@njglyy.com

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Song Liu

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

DANCE-04

## Study information

### Scientific Title

Efficacy and safety of subserosal carbon nanoparticles navigated radical gastrectomy

### Acronym

DANCE-04

### Study objectives

Subserosal carbon nanoparticles is safer and more efficient than submucosal carbon nanoparticles in radical gastrectomy

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 08/12/2022, Ethics committee of Nanjing Drum Tower Hospital, the Affiliated Hospital of Nanjing University Medical School (321 Zhongshan Rd, Nanjing, 210008, China; +86 (0)25 83106666; irb\_dth@outlook.com), ref: 2023-372-02

## **Study design**

Randomized interventional prospective single-center clinical trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment, Safety, Efficacy

## **Health condition(s) or problem(s) studied**

Radical gastrectomy for patients with gastric cancer

## **Interventions**

All participants will be randomized into two groups. Group 1: Subserosal injection of carbon nanoparticles for lymph node visualization. Group 2: Submucosal injection of carbon nanoparticles for lymph node visualization.

Method of randomization: simple randomization method using a computer-generated random number to assign each participant to a specific group.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Number of retrieved lymph nodes measured by pathological examination immediately after radical gastrectomy

## **Key secondary outcome(s)**

1. Number of metastatic lymph nodes measured by pathological examination immediately after radical gastrectomy
2. Sensitivity and specificity of carbon nanoparticles staining for the diagnosis of metastatic lymph nodes, measured by pathological examination immediately after radical gastrectomy
3. 3-year disease-free survival (DFS), 3-year relapse-free survival (RFS), 3-year overall survival (OS), measured by outpatient clinic or telephone follow-up at 3 years after surgery
4. Postoperative complications measured by Clavien-Dindo classification at 1, 3, and 7 days after surgery

## **Completion date**

31/12/2025

# **Eligibility**

## **Key inclusion criteria**

1. Between 18 and 75 years old
2. cT1-4a, cNany, cM0 according to the AJCC classification (version 7.0) before surgery
3. Absence of adjacent organ invasion

4. Performance status (ECOG score) 0 or 1, ASA I-III
5. Consent of participation
6. Distal or total radical gastrectomy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

75 years

**Sex**

All

**Total final enrolment**

99

**Key exclusion criteria**

1. Pregnancy or lactation period
2. Severe mental illness
3. Previous upper abdomen surgery excluding laparoscopic cholecystectomy
4. Previous gastric ESD or EMR history
5. Refusal to laparoscopy
6. Previous iodine allergy
7. Peri-gastric LNs larger than 3cm in preoperative CT or MR
8. Other malignancy in recent 5 years
9. Neoadjuvant therapy for gastric cancer
10. Unstable angina pectoris or myocardial infarction in recent 6 months
11. FEV1 less than 50% of predicted value
12. Systemic corticosteroid therapy in recent 1 month
13. Emergent surgery due to acute bleeding, perforation or obstruction
14. Convert to open surgery
15. Concomitant surgery excluding appendectomy or cholecystectomy

**Date of first enrolment**

01/08/2023

**Date of final enrolment**

31/12/2024

**Locations**

**Countries of recruitment**

China

**Study participating centre**

Nanjing Drum Tower Hospital, the Affiliated Hospital of Nanjing University Medical School

321 Zhongshan Rd

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China

210008

**Sponsor information****Organisation**

Nanjing Drum Tower Hospital

**ROR**

<https://ror.org/026axqv54>

**Funder(s)****Funder type**

Government

**Funder Name**

National Natural Science Foundation of China

**Alternative Name(s)**

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

China

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during this study will be published as a supplement to the results publication.

## IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		19/05/2025	21/05/2025	Yes	No