ISRCTN11247387 https://doi.org/10.1186/ISRCTN11247387

# Subserosal carbon nanoparticles for gastrectomy

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 29/07/2023 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 02/08/2023 | Ongoing | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 21/05/2025 | Cancer | |

## 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

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment, Safety, Efficacy

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

## Secondary outcome measures
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

### Overall study start date
01/09/2022

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
75 Years

### Sex
Both

### Target number of participants
100

### 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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210008

## Sponsor information

### Organisation
Nanjing Drum Tower Hospital

### Sponsor details
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### Sponsor type
Hospital/treatment centre

### Website
http://www.njglyy.com/en/

**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 Wěiyuánhuì, NSFC, NNSF, NNSFC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
China

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**
31/12/2025

**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? |
|---|---|---|---|---|---|
| Results article | | 19/05/2025 | 21/05/2025 | Yes | No |