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	Completed	[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

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Additional identifiers

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

Primary study design
Interventional

Study design
Randomized interventional prospective single-center clinical trial

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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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 Wěiyuánhuì, , 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?
Results article		19/05/2025	21/05/2025	Yes	No