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Single-port nipple-sparing subcutaneous mastectomy with immediate prosthetic breast reconstruction for cancer

Submission date
21/11/2022

Recruitment status
No longer recruiting

Registration date
30/12/2022

Overall study status
Completed

Last Edited
28/12/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Nipple-sparing subcutaneous mastectomy (NSM) combined with immediate prosthetic reconstruction (IPR) is an important surgery for breast cancer. Conventional open NSM-IPR (C-NSM-IPR) leaves long and ugly surgical scars on the skin, which are under the tension of the prosthesis. And this can result in incision splitting or prosthetic exposure. Some incisions around the areola could result in necrosis of the nipple-areola complex. A new surgical technique was designed called single-port insufflation endoscopic (SIE)-NSM-IPR to try to prevent these problems. The incision is short and is conducted on the lateral aspect of the chest wall. This allows the resection to be completed with an incision that is not in a high-tension area. The scar is short, which may improve its appearance and reduce surgical complications. This was a retrospective study that aimed to compare the oncologic safety, aesthetic outcome and perioperative results of SIE-NSM-IPR with those of C-NSM-IPR.

Who can participate?
Patients aged between 18 and 70 years old who received NSM-IPR between January 2014 and December 2019 at Beijing Friendship Hospital affiliated with Capital Medical University

What does the study involve?
This study investigated the oncologic safety, aesthetic outcome and perioperative results of two kinds of surgery, SIE-NSM-IPR and C-NSM-IPR using a questionnaire and data collected from the medical records.

What are the possible benefits and risks of participating?
This is a retrospective study. There are no benefits or risks to participating.

Where is the study run from?
Beijing Friendship Hospital, Capital Medical University (China)

When is the study starting and how long is it expected to run for?
November 2019 to November 2022

Who is funding the study?
1. Capital's Funds for Health Improvement and Research (2020-2-1112) (China)
2. Research Foundation of Beijing Friendship Hospital, Capital Medical University (yyqdkt2018-11) (China)

Who is the main contact?
Guoxuan Gao, aliceggx@163.com

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Single-port nipple-sparing subcutaneous mastectomy with immediate prosthetic breast reconstruction for cancer: A retrospective cohort study (SPINER)

Acronym
SPINER

Study objectives
Single-port insufflation endoscopic nipple-sparing subcutaneous mastectomy combined with immediate reconstruction using prosthesis implantation is safe with high quality of life for breast cancer patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/05/2020, Ethics Committee of Beijing Friendship Hospital affiliated with Capital Medical University (95 Yong-an Road, Xi-Cheng District, Beijing 100050, China; +86 (10) -63139017; wykchangfeng@163.com), ref: 2019-P2-052-02

Study design
Retrospective cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
This study was a retrospective cohort study. Single-port insufflation endoscopic nipple-sparing subcutaneous mastectomy combined with immediate prosthetic reconstruction (SIE-NSM-IPR) using prosthesis implantation was the test group. In this group, a small single-port incision on the side chest wall is used to perform resection of the gland and implant the prosthesis at the same time; this minimises the surgical scar and ensures that it is not in a high-tension area. Conventional open-nipple and areola-sparing subcutaneous mastectomy combined with immediate reconstruction using prosthesis implantation (C-NSM-IPR) was the control group, which leaves noticeable surgical scars on the surface of the breast. Patients underwent surgery for breast cancer between January 2014 and December 2019 at Beijing Friendship Hospital affiliated with Capital Medical University.

Continuous variables with normal distribution will be reported as mean values (standard deviation [SD]). Non-normal variables will be presented as medians (interquartile range [IQR]). The means of two continuous normally distributed variables are compared using independent samples Student’s t-test. Mann-Whitney U test will be used to compare the means of 2 groups of variables not normally distributed. Log-rank tests will be used to compare the overall survival (OS) and disease-free survival (DFS) rates between the groups. A p-value less than 0.05 will be considered statistically significant. All reported p-values will be two-sided. The statistical analyses will be performed using SPSS v24 (IBM Corp., Chicago, IL, USA).

Intervention Type
Procedure/Surgery

Primary outcome(s)

Postoperative complications measured using data sources collected from the medical records according to the Clavien-Dindo classification 1 month after surgery

Key secondary outcome(s))
1. Aesthetic satisfaction of patients measured using the BREAST-Q questionnaire 6 months after surgery
2. Survival data measured using data sources collected from the medical records for all patients who were followed up at the outpatient clinic re-examination or through a telephone call every 6 months to record whether there was local recurrence or metastasis

Completion date
01/11/2022

Eligibility

Key inclusion criteria
1. Aged between 18 to 70 years old
2. Diagnosis of stage I or II invasive breast carcinoma or carcinoma in situ
3. Original lesion ≤3 cm in diameter
4. Distance between the lesion and the nipple-areola complex ≥2 cm
5. Clinically negative axillary nodes
6. Tumor constrained to the mammary gland
7. Tumor is not invading the nipple-areola complex or the skin
8. Negative sentinel lymph node biopsy
9. Eastern Cooperative Oncology Group score from 0-2
10. Patient not suitable for breast-conserving surgery and not requesting mastectomy and breast reconstruction

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Total final enrolment
64

Key exclusion criteria
Positive sentinel lymph node biopsy

Date of first enrolment
01/01/2022

Date of final enrolment
01/11/2022

Locations

Countries of recruitment
China

Study participating centre
Beijing Friendship Hospital affiliated with Capital Medical University
No. 95, Yong An Road
Xicheng District
Beijing
China
100050

Sponsor information

Organisation
Beijing Friendship Hospital

ROR
https://ror.org/053qy4437

Organisation
Beijing Municipal Health Bureau

ROR
https://ror.org/0374a5s68

Funder(s)

Funder type
Government

Funder Name
Capital’s Funds for Health Improvement and Research

Funder Name
Beijing Friendship Hospital, Capital Medical University

Alternative Name(s)
, , Beijing Friendship Hospital, BFH

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from aliceggx@163.com.
The type of data that will be shared: Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices)
Timing for availability: Beginning 12 months and ending 36 months following article publication
Whether consent from participants was required and obtained: Yes
Comments on data anonymization: All data were anonymized
Any ethical or legal restrictions: Investigators whose proposed use of these data has been approved by an independent review committee identified for this purpose
Any additional comment: No

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes