

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

<b>Submission date</b> 21/11/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/12/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/12/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 (yyqdk2018-11) (China)

Who is the main contact?

Guoxuan Gao, aliceggx@163.com

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Guoxuan Gao

### ORCID ID

<https://orcid.org/0000-0001-7115-5972>

### Contact details

Capital Medical University

No. 95, Yong An Road

Xicheng District

Beijing

China

100050

+86 (0)1063138712

aliceggx@163.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

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  $\leq 3$  cm in diameter
4. Distance between the lesion and the nipple-areola complex  $\geq 2$  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