

# Feasibility of lymph node removal after chemotherapy in breast cancer patients

<b>Submission date</b> 23/10/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/10/2019	<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

Axillary lymph node evaluation is one of the important indicators for clinical pathological staging of breast cancer. However, for patients receiving neoadjuvant chemotherapy, the timing of sentinel lymph node biopsy is still controversial. This study will investigate the feasibility and safety of sentinel lymph node biopsy in Chinese patients with cN1 breast cancer who undergo routine radical surgery after neoadjuvant chemotherapy under current medical conditions in China

### Who can participate?

Eligible patients with cN1 breast cancer at 18-70 years of age of either sex

### What does the study involve?

All enrolled patients will undergo neoadjuvant chemotherapy, radical mastectomy and intraoperative sentinel lymph node biopsy. All enrolled patients will receive this treatment and undergo lymph node diagnosis and evaluation after surgery

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

Eligible patients included in this study may not get direct benefits, but they will get more medical attention from investigators. Lymph node tracers methylene blue and carbon nanoparticles can cause local skin necrosis, but this risk can be avoided by rigorous intraoperative operation

### Where is the study run from?

1. The First Hospital of China Medical University (lead center)
2. Shengjing Hospital of China Medical University
3. Liaoning Cancer Hospital & Institute
4. Affiliated Zhongshan Hospital of Dalian University
5. The Second Hospital of Dalian Medical University
6. The Fourth Affiliated Hospital of China Medical University, China.

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

The anticipated start date of this study is December 2019 and the anticipated end date of this study is February 2022. The duration of the trial is approximate 2 years.

Who is funding the study?

This study will be funded by Liaoning Province Distinguished Professor Fund (LWF [2017] No.3)

Who is the main contact?

Lei Zhang, Project secretary  
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## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

1.0

## Study information

### Scientific Title

Feasibility of sentinel lymph node biopsy using dye alone method in Chinese patients with cN1 breast cancer after neoadjuvant chemotherapy evaluated by clinical physical examination and three-dimensional ultrasound: a prospective, multicenter, diagnostic trial

### **Study objectives**

For patients receiving neoadjuvant chemotherapy, the timing of sentinel lymph node biopsy is still controversial. Although some results have been achieved in this respect, the results also have some limitations. Based on this, this study will investigate the feasibility and safety of sentinel lymph node biopsy in Chinese patients with cN1 breast cancer who undergo routine radical axillary lymph node dissection after neoadjuvant chemotherapy under current medical conditions in China

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 06/08/2019, Medical Ethics Committee, First Hospital of China Medical University (No. 155 Nanjing North Street, Heping District, Shenyang, Liaoning Province, China; yykyk@vip.163.com; +86-024-83282837), ref: KLS[2019]2019-193-2

### **Study design**

Prospective multicenter diagnostic trial

### **Primary study design**

Observational

### **Secondary study design**

Case series

### **Study setting(s)**

Hospital

### **Study type(s)**

Diagnostic

### **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**

Breast cancer

### **Interventions**

The enrolled patients will receive neoadjuvant chemotherapy. After neoadjuvant chemotherapy and before radical axillary lymph node dissection, sentinel lymph node tracer will be injected. Before routine axillary lymph node dissection, sentinel lymph node biopsy will be performed. The dissected sentinel lymph nodes and other axillary lymph nodes will be marked separately for routine pathological examination.

### **Intervention Type**

## Procedure/Surgery

### Primary outcome measure

False negative rate of sentinel lymph node biopsy at postoperative day one, according to pathological results and referencing to gold standard, false negative rate of sentinel lymph nodes = (number of patients having false negative sentinel lymph nodes/number of patients having gold standard results) × 100%

### Secondary outcome measures

1. At postoperative day one, the relationship between each influential factor (neoadjuvant efficacy, tumor location, surgical procedure, number of sentinel lymph nodes detected, molecular subtypes of breast cancer (luminal A, luminal B, HER2-positive, triple-negative)) and the results of sentinel lymph node biopsy after neoadjuvant chemotherapy
2. Adverse events during the trial

### Overall study start date

01/03/2019

### Completion date

20/02/2022

## Eligibility

### Key inclusion criteria

1. Women, age at 18-70 years
2. Primary invasive breast adenocarcinoma confirmed by physical examination, breast color Doppler ultrasound, mammography, MRI evaluation, and hollow needle histological examination. Before treatment, all patients have cN1 lymph nodes, i.e., subaxillary enlarged lymph nodes palpable by clinical examination and/or suspected positive enlarged lymph nodes revealed by related examinations, which are not considered as metastatic lymph nodes;
3. Not previously received treatment for breast cancer, agree to participate in the study, and have good compliance
4. The Eastern Cooperative Oncology Group (ECOG) performance status grade 0-2
5. Before treatment, the results of hematological and biochemical examinations should meet the following conditions: white blood cells  $\geq 4.0 \times 10^9/L$ , absolute neutrophil count  $\geq 1.5 \times 10^9/L$ , platelet count  $\geq 100 \times 10^9/L$ , hemoglobin  $\geq 90 \text{ g/L}$ , glutathione transaminase, alanine transaminase  $\leq 1.5 \times$  upper limit of normal, creatinine  $\leq 1.5 \times$  upper limit of normal, total bilirubin  $\leq 1.5 \times$  upper limit of normal
6. No serious heart, liver and kidney diseases

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Upper age limit

70 Years

**Sex**

Female

**Target number of participants**

500

**Key exclusion criteria**

1. No provision of written informed consent
2. Lactating or pregnant women
3. Confirmed distant metastasis of breast cancer
4. Sensory or motor neuropathy, or those diagnosed with psychiatric disorder
5. Confirmed cardiovascular diseases, serious concomitant diseases or active infections including known human immunodeficiency virus infection
6. History of other cancers
7. Allergic to drugs and excipients involved in tracers and neoadjuvant chemotherapy

**Date of first enrolment**

30/12/2019

**Date of final enrolment**

30/12/2021

**Locations**

**Countries of recruitment**

China

**Study participating centre**

**The First Hospital of China Medical University**

No.155 Nanjing North Street

Heping District

Shenyang

Liaoning Province

Shenyang

China

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**Study participating centre**

**Liaoning Cancer Hospital & Institute**

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**Study participating centre**

**Affiliated Zhongshan Hospital of Dalian University**

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Liaoning Province  
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**Study participating centre**

**The Second Hospital of Dalian Medical University**

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**Study participating centre**

**The Fourth Affiliated Hospital of China Medical University**

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## **Sponsor information**

**Organisation**

The First Hospital of China Medical University

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/04wjghj95>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Liaoning Province Distinguished Professor Fund of China (LWF [2017] No.3)

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

30/06/2023

**Individual participant data (IPD) sharing plan**

All data generated or analysed during this study will be included in the subsequent results publication

**IPD sharing plan summary**

Other