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Feasibility of lymph node removal after chemotherapy in breast cancer patients

Submission date 23/10/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/10/2019	**Overall study status** Completed	
Last Edited 28/10/2019	**Condition category** Cancer	

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
zhl656144@163.com

Contact information

Type(s)
Public

Contact name
Prof Bo Chen

ORCID ID
http://orcid.org/0000-0001-6372-8806

Contact details
No.155 Nanjing North Street
Heping District
Shenyang
Liaoning Province
Shenyang
China
110001
+861 5904025211
chbyxl@163.com

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 ≥ 4.0 x 109/L, absolute neutrophil count ≥ 1.5 x 109 /L, platelet count ≥ 100 x 109/L, hemoglobin ≥ 90 g/L, glutathione transaminase, alanine transaminase ≤ 1.5 x upper limit of normal, creatinine ≤ 1.5 x upper limit of normal, total bilirubin ≤ 1.5 x 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
110001

Study participating centre
Liaoning Cancer Hospital & Institute
No. 44 Xiaoheyan Road
Dadong District
Shenyang
Liaoning Province

Shenyang
China
110042

Study participating centre
Affiliated Zhongshan Hospital of Dalian University
No. 6 Jiefang Street
Zhongshan District
Dalian
Liaoning Province
Dalian
China
116004

Study participating centre
The Second Hospital of Dalian Medical University
No. 467 Zhongshan Road
Shahekou District
Dalian
Liaoning Province
Dalian
China
116023

Study participating centre
The Fourth Affiliated Hospital of China Medical University
No. 4 Chongshan Road
Huanggu District
Shenyang
Liaoning Province
Shenyang
China
110033

Sponsor information

Organisation
The First Hospital of China Medical University

Sponsor details

No.155 Nanjing North Street
Heping District
Shenyang
Liaoning Province
Shenyang
China
110001
+861 5904025211
chbyxl@163.com

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