

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Preliminary study to evaluate the effectiveness of direct injection of Indian ink and blue methylene in the involved and suspected lymph nodes before and after neoadjuvant chemotherapy in patients with breast cancer and the practical use of this method in detecting these lymph nodes during surgery.

Protocol summary

Study aim

Preliminary study to evaluate the effectiveness of direct injection of Indian ink and blue methylene in the involved and suspected lymph nodes before and after neoadjuvant chemotherapy in patients with breast cancer and the practical use of this method in detecting these lymph nodes during surgery.

Design

This preliminary experimental study will be performed at the Cancer Institute of Imam Khomeini Hospital during the year 1401. Breast cancer patients who are candidates for neoadjuvant chemotherapy will enter the study. The sampling method is convenience sampling.

Settings and conduct

Patients are divided into two groups according to the time of neoadjuvant chemotherapy. 0/2 cc of Indian ink will be injected in involved lymph nodes under the ultrasound guide. In the next stage, the patient undergoes neo-adjuvant chemotherapy and then, the axillary ultrasound is performed and the procedure will be continued according to the following algorithm. In patients who have received neo-adjuvant before, whether their axillary lymph nodes are involved or not, the ultrasound will be repeated and the process will continue according to the attached algorithm. The details of the lymph nodes after extraction will be written on the relevant container and will be examined by an experienced pathologist.

Participants/Inclusion and exclusion criteria

Breast cancer patients who have finished neoadjuvant chemotherapy and had involved N1-N2 lymph nodes confirmed by pathology or ultrasonography

Intervention groups

Breast cancer patients with positive lymph node before

chemotherapy admitted for surgery after chemotherapy.

Main outcome variables

Successful injection of Indian ink
Successful injection of methylene blue
Successfully finding a stained LN with Indian ink
Successfully finding lymph nodes stained with methylene blue
Involvement of positive lymph nodes after chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180720040533N3**

Registration date: **2022-12-06, 1401/09/15**

Registration timing: **retrospective**

Last update: **2022-12-06, 1401/09/15**

Update count: **0**

Registration date

2022-12-06, 1401/09/15

Registrant information

Name

Farzad Vaghef Davari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2213 5448

Email address

fvdavari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preliminary study to evaluate the effectiveness of direct injection of Indian ink and blue methylene in the involved and suspected lymph nodes before and after neoadjuvant chemotherapy in patients with breast cancer and the practical use of this method in detecting these lymph nodes during surgery.

Public title

The effect of Indian ink on the identification of involved lymph nodes in breast cancer

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Breast cancer patients that are candidates for neoadjuvant chemotherapy Underwent previous chemotherapy for any reason or candidate for current chemotherapy due to lymph node Involvement Involvement of lymph nodes confirmed by pathology. Involvement of lymph nodes (N1 or N2a)

Exclusion criteria:

Extensive lymph node (N2b or N30) or skin involvement Failure to follow the treatment by the patient after the intervention

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran university of medical sciences

Street address

Ethics Committee , Central Building of University, Ghods St. , Keshavarz Bld.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1370

Health conditions studied**1****Description of health condition studied**

breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Finding the involved lymph nodes after neoadjuvant chemotherapy

Timepoint

Indian ink injection the day before surgery and the morning of surgery in one group and also before the beginning of of neoadjuvant chemotherapy in the other group

Method of measurement

details of the lymph nodes will be written on the relevant container after the excision and will be examined by an experienced pathologist, and finally the desired variables will be entered directly in the Data Sheet of SPSS program.

Secondary outcomes**1****Description**

Success in injecting Indian ink, success in injecting methylene blue , succeeding in finding lymph nodes stained with Indian ink, succeeding in finding lymph node stained with methylene blue, involvement of affected

lymph node after chemotherapy, involvement of suspected lymph node after chemotherapy

Timepoint

After the intervention in the group that has received chemotherapy and after the completion of chemotherapy in the group that will be received chemotherapy

Method of measurement

details of the lymph nodes will be written on the relevant container after the excision and will be examined by an experienced pathologist, and finally the desired variables will be entered directly in the Data Sheet of SPSS program.

Intervention groups

1

Description

Intervention group: breast cancer patients who are candidates for neoadjuvant chemotherapy. If the lymph nodes are involved, the affected lymph nodes will be injected with 0.2 cc of Indian ink under an ultrasound guide (injection is done with an insulin syringe and then 0.1 cc of distilled water is injected to clean the syringe)

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Farzad Vaghef Davari

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Cancer Institute, Imam Khomeini Hospital, Keshavarz Bld.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farzad Vaghef Davari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no reason

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available