

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### comparing Prevalence of lymphedema after Axillary Reverse Mapping by methylen blue or without methylen blue in patients with breast neoplasm

#### Protocol summary

##### Study aim

compare relative frequency of lymphedema after axillary reverse mapping by methylen blue or without methylen blue in breast neoplasm patients

##### Design

clinical trial with control groups, parallel groups , without blinding, not randomised with 160 patients

##### Settings and conduct

after injection of 1.0mCi unfiltered technetium sulfur colloid to all patients , attending to their clinical condition ,they were divided in 2 groups. one with methylene blue injection and one without injecting(only studying with gamma detector). blinding was not needed .

##### Participants/Inclusion and exclusion criteria

breast cancer , candidate for Sentinel Lymph Node Biopsy(SLNB) +Axillary Reverse Mapping(ARM) ±Axillary Lymph Node Dissection(ALND) , operable tumor

##### Intervention groups

in intervention group first methylen blue will be injected and using this coloring methode , sentinel lymph node will be detected and dissected and lymphedema incidence will be detected after that in control group we do not inject methylen blue and sentinel lymph node will be detected just by using gamma detector and then dissected

##### Main outcome variables

breast cancer / independent SLNB / dependent ARM / dependent ALND/ dependent arm circumference / dependent affected site / dependent affected anatomical region / dependent tumor size/ dependent surgery duration/ dependent number of dissected lymph nodes/ dependent age / background body mass index/background

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200909048672N1**

Registration date: **2020-12-06, 1399/09/16**

Registration timing: **retrospective**

Last update: **2020-12-06, 1399/09/16**

Update count: **0**

##### Registration date

2020-12-06, 1399/09/16

##### Registrant information

###### Name

Reza Eshraghi samani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3668 0042

###### Email address

eshraghireza@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2020-10-22, 1399/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparing Prevalence of lymphedema after Axillary Reverse Mapping by methylen blue or without methylen blue in patients with breast neoplasm

##### Public title

investigate Prevalence of lymphedema after breast neoplasm surgery

#### **Purpose**

Diagnostic

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

breast cancer SLNB+ARM±ALND candidate able to surgery

##### **Exclusion criteria:**

previous chemotherapy previous radiotherapy previous axillary surgery

#### **Age**

No age limit

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: **160**

#### **Randomization (investigator's opinion)**

Not randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

##### **Ethics committee**

###### **Name of ethics committee**

Ethical committee of Esfahan university of medical science

###### **Street address**

Hezar Jarib

###### **City**

Esfahan

###### **Province**

Isfahan

###### **Postal code**

8174673461

##### **Approval date**

2020-05-14, 1399/02/25

##### **Ethics committee reference number**

IR.MUI.MED.REC.1399.148

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

breast cancer

##### **ICD-10 code**

C50

##### **ICD-10 code description**

Malignant neoplasm of breast

#### 2

##### **Description of health condition studied**

lymphedema

##### **ICD-10 code**

I97.2

##### **ICD-10 code description**

Postmastectomy lymphedema syndrome

### **Primary outcomes**

#### 1

##### **Description**

arm circumference

##### **Timepoint**

at the beginning and six month

##### **Method of measurement**

measuring with meter

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

##### **Description**

first we inject methylen blue to patients in this group and with colored path that methylen blue makes , axillary lymph node mapping will be done. then using this mapping sentinel lymph node will be detected and dissected . prevalence of lymphedema will be measured after all this stages

##### **Category**

Diagnosis

#### 2

##### **Description**

in this group we do not inject methylen blue and mapping will be done just by gamma detector . sentinel lymph node will be dissected and prevalence of lymphedema will be measured

##### **Category**

Diagnosis

### **Recruitment centers**

#### 1

Recruitment center

**Name of recruitment center**  
Seyed al Shohada Hospital  
**Full name of responsible person**  
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**Full name of responsible person**  
Reza Eshraghi Samani  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Beheshte Toghiani  
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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**  
Esfahan 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**  
Esfahan University of Medical Sciences

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

when all patients personal data become unrecognizable ,  
all collected data will be published

**When the data will become available and for how long**

6 month after article published

**To whom data/document is available**

researchers work in scientific institues

**Under which criteria data/document could be used**

other scientific purposes

**From where data/document is obtainable**

reza eshraghi samani

**What processes are involved for a request to access data/document**

to recieve data , requester should send an email to dr  
esgrahi , then we will qualify his/her identity and verify  
his/her request (takes about 1 month) and send him/her  
requested data

**Comments**