Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Ẹshraghi samani
Name of organization / entity
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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 axilary 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
Isfehan

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Full name of responsible person
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Position
Associate Professor
Latest degree
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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