

# The value of Isosulfan Blue dye in addition to Isotope scan in Sentinel lymph Node biopsy for breast cancer patients with a positive lymphoscintigraphy.

<b>Submission date</b> 13/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/03/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

**Scientific Title**  
The value of Isosulfan Blue dye in addition to Isotope scan in Sentinel lymph Node biopsy for breast cancer patients with a positive lymphoscintigraphy: A randomised controlled trial

**Study objectives**

Patients with breast cancer undergoing Sentinel lymph node biopsy (SLN) biopsy may not need the Isosulphan dye to identify the SLN if the node is/are identified on the lymphoscintigram when the radioisotope is used.

### **Ethics approval required**

Old ethics approval format

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

Ethics and Medical Research Committee of St. Vincent's University Hospital, 16/02/2010, ref: 16/02/10

### **Study design**

Randomised open-label controlled parallel-group trial

### **Primary study design**

Interventional

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

Diagnostic

### **Health condition(s) or problem(s) studied**

Breast Cancer

### **Interventions**

Patients going for SLN will have a lymphoscintigram. if the SLNs is identified the patients will be randomised to either receive or not receive the isosulphan blue dye.

The duration of the recruitment period will be 1.5-2 years. The total duration of follow up will be 2 months post intervention.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

The effect of the omission of the blue dye on the identification of SLN if the scintigram is positive

### **Key secondary outcome(s)**

1. Complications from the blue dye including tattoo of the skin
2. Cost effectiveness

### **Completion date**

01/03/2012

## **Eligibility**

### **Key inclusion criteria**

1. Age >18 years old and <90 years
2. Breast cancer (stages I, II and III) and a sentinel Lymph node biopsy is required as recommended at the multidisciplinary breast cancer meeting
3. A pre-operative lymphoscintigram with a single node or a few nodes present

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Key exclusion criteria**

1. Age outside the inclusion criteria above
2. Stage IV breast cancer, and primary chemotherapy patients
3. Patients with negative scintigrams
4. Patients with a large number of nodes on the Scintigram >3 LNs
5. Patients who cannot give consent

**Date of first enrolment**

01/03/2010

**Date of final enrolment**

01/03/2012

**Locations****Countries of recruitment**

Ireland

**Study participating centre**

St. Vincent's University Hospital

Dublin

Ireland

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**Sponsor information**

## Organisation

St. Vincent's University Hospital (Ireland)

## ROR

<https://ror.org/029tkqm80>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

St. Vincent's University Hospital (Ireland) - Department of Surgery

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2015		Yes	No
<a href="#">Abstract results</a>	results	01/12/2013		No	No