

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Enda McDermott

Contact details

St. Vincent's University Hospital
Elm Park
Dublin
Ireland
4

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/03/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

734

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

4

Sponsor information

Organisation

St. Vincent's University Hospital (Ireland)

Sponsor details

Department of Surgery

Elm Park

Dublin

Ireland

4

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Abstract results	results	01/12/2013		No	No
Results article	results	01/08/2015		Yes	No