ISRCTN98849733 https://doi.org/10.1186/ISRCTN98849733

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

Registration date
18/06/2010

Overall study status
Completed

Last Edited
31/03/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

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?
Results article	results	01/08/2015		Yes	No
Abstract results	results	01/12/2013		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes