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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/06/2010	**Overall study status** Completed	
Last Edited 31/03/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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