ISRCTN17778965 https://doi.org/10.1186/ISRCTN17778965

Randomised trial of LightPath Imaging in breast cancer surgery

Submission date 25/01/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/02/2016	**Overall study status** Completed	
Last Edited 05/05/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-the-use-of-the-lightpath-imaging-system-during-breast-surgery-lpm-007

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02666079

Secondary identifying numbers

LPM-007

Study information

Scientific Title
A randomised, controlled, multi-centre clinical study to evaluate the outcomes following the intra-operative use of the LightPathTM Imaging System compared to standard practice in wide local excision (WLE) for breast cancer

Study objectives
Use of the LightPath™ Imaging System will reduce the rate of re-operations compared to standard of care surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Dulwich Research Ethics Committee, 04/04/2016, ref: 16/LO/0414
Amendment 1: 13/06/2016
Amendment 2: 28/07/2016

Study design
Prospective randomised controlled multi-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Female participants with a diagnosis of invasive breast cancer or ductal carcinoma in situ (DCIS) scheduled to have wide local excision (WLE) +/- sentinel lymph node biopsy (SLNB) or axillary lymph node dissection (ALND) will be screened, and if eligible randomised (1:1) to either: the 18F-FDG plus LightPath™ Imaging System arm (Treatment Arm) or the arm without 18F-FDG and LightPath™ (control arm).

Participants in both arms will have standard of care WLE of the primary tumour. Following resection, the WLE specimen, shavings (if any) and lymph nodes will be examined using the LightPath™ Imaging System (Treatment Arm only). If the surgeons detect a positive signal they may perform extra cavity shavings of the resection cavity area corresponding to the positive signal area (up to a maximum thickness of 10mm).

Axillary SLNB will be performed according to local practice. Sentinel lymph nodes (SLNs) will be examined using the LightPath™ Imaging System (Treatment Arm only). Where clinically indicated, ALND will be performed as per standard of care. At the time this protocol was finalised LightPath™ data from involved lymph nodes sufficient to support recommendations were not available. For this reason, LightPath™ Image results will not be used to direct ALND.

The WLE surgery constitutes the total duration of treatment in this study. Following surgery, the study site's multidisciplinary team (MDT) will decide whether or not to re-operate at the index location (breast). This is the study's primary outcome, and according to local practice the decision is made between 1 and 12 weeks after surgery.

At study sites where long-term follow-up is standard of care participants will return for study follow-up visits at 1-12 weeks, 6 and 12 months after completion of the initially planned surgery. After this the participants will be followed up annually to 60 months after the initial surgery.

Intervention Type
Device

Primary outcome measure
Primary outcome as of 30/08/2016:
Decision by the study site's multidisciplinary team (MDT) to re-operate at index location (breast). Assessed within 1-6 weeks, according to local practice.

Original primary outcome:
Decision by the study site's multidisciplinary team (MDT) to re-operate at index location (breast) assessed within 1-12 weeks, according to local practice

Secondary outcome measures
Secondary outcomes as of 30/08/2016:
1. Initial surgery (deviations on decision to re-operate, volume of tissue excised, complete surgical resection, normalised total tissue volume, duration of surgical operation)
2. Safety (adverse events)
3. Patient Outcomes (EORTC QLQ-C30, EORTC QLQ-C30, HADS and EQ-5D at screening, 3, 6, 12 and 24 months follow-up and cosmesis outcome)
4. Use of the LightPath™ Imaging System (Agreement between LightPath™ images and histology, Ease of Use Questionnaire, radiation safety, independent review of LightPath™ images)
5. Breast cancer (re-operation rate, time to recurrence, survival, overall survival, disease specific survival)

Original secondary outcomes:
1. Re-operation rate at index location, as directed by decision to re-operate and logistics
2. Volume of primary lump and lump plus shavings, data collected at initial surgery
3. Quality of Life (QoL) assessment including cosmetic assessment (at screening, 1-12 weeks, 6 months and 12 months)

4. In LightPath™ arm only: Radiation dosimetry on operating room and recovery area staff. Data collected at initial surgery
5. Proportion of LightPath™ Image positive margins that correlate with histology. Data collected at initial surgery
6. Proportion of LightPath™ Image positive shavings that correlate with histology. Data collected at initial surgery
7. In LightPath™ arm only: Ease-of use of LightPathTM system. Data collected on day of surgery
8. Re-intervention for residual tumour
9. Cosmesis based on quality of life (QoL) questionnaire (at screening, 1-12 weeks, 6 months and 12 months)
10. Lymph node involvement by LightPath™ Image (compared with histology: macrometastasis, micrometastasis, or isolated tumour cells). Data collected by 3 months after initial surgery
11. Number of patients with ipsilateral breast tumour recurrence (IBTR) during follow-up. Data collected by 3 months
12. Disease-free survival. Data collected by 3 months
13. In LightPath™ arm only: Study-related adverse events. Data collected by 3 months after initial surgery
14. Re-intervention costs/health economics. Re-intervention by +3 months post initial study surgery
15. Overall survival. Data collected by 3 months

Overall study start date
25/01/2016

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Signed an informed consent form prior to any study related activity
2. Able to give voluntary, written informed consent to participate in this study.
3. Able to understand this study and are willing to complete all the study assessments
4. Female subjects ≥18 years of age with a diagnosis of invasive breast cancer or DCIS
5. Those who have unifocal disease in one quadrant of the breast, not including the nipple
6. Those who have a tumour diameter of at least 10 mm (if measurable by mammography)
7. Scheduled for WLE +/- SLNB or ALND
8. Of childbearing age must have a negative pregnancy test (by Beta HCG qualitative analysis), or must have had a history of a surgical sterilisation, or must give history of no menses in the past twelve months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Female

Target number of participants
442

Total final enrolment
66

Key exclusion criteria
Subjects who:
1. Have had surgery in the operated breast in the past 2 years
2. Have had radiotherapy in the operated breast
3. Have had neoadjuvant systemic therapy
4. Have had systemic chemotherapy in the past two years
5. Not suitable for WLE
6. Have blood glucose level ≥12 mmol/L
7. Have known hypersensitivity to 18F-FDG
8. Planned perioperative or Intraoperative Radiation Therapy (IORT) or brachytherapy
9. Pregnant or lactating
10. Have an existing medical condition that would compromise their participation in the study
11. Have participated in a clinical study in the last 2 months
12. Current or active history of other known cancer

Date of first enrolment
01/10/2016

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
England

Germany

United Kingdom

Wales

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 9RT

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospital Llandough
Penlan Road
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CF64 2XX

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Kliniken Essen-Mitte
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Sponsor information

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Sponsor type
Industry

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http://www.lightpointmedical.com/

ROR
https://ror.org/04zym2g32

Funder(s)

Funder type
Government

Funder Name
European Commission, Horizon 2020, Executive Agency for Small & Medium-sized Enterprises

Funder Name
Lightpoint Medical Ltd

Results and Publications

Publication and dissemination plan

The sponsor will register the study and post study results on publicly accessible websites (including www.ClinicalTrials.gov, www.isrctn.org). All data and results and all intellectual property rights in the data and results derived from the study will be the property of the sponsor, who may utilise the data in various ways, such as for submission to government regulatory authorities or disclosure to other Investigators.

The sponsor will ensure that both positive and negative results of the study will be published in scientific journals and/or trial registers or websites as required. The sponsor recognises the right of the participants to be informed about the study results and will take appropriate measures to inform any participant who wishes to know about the study results. Any manuscript or abstract produced by an investigator must be provided to the sponsor for review 30 days prior to submission. Individual participant identity cannot be divulged in any publication. Details of publications will be addressed in the Investigator Agreement.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	pilot study results	18/03/2021	22/03/2021	Yes	No
Plain English results			05/05/2022	No	Yes
HRA research summary			28/06/2023	No	No