

Randomised trial of LightPath Imaging in breast cancer surgery

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

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

ClinicalTrials.gov (NCT)

NCT02666079

Protocol serial number

LPM-007

Study information

Scientific Title

A randomised, controlled, multi-centre clinical study to evaluate the outcomes following the intra-operative use of the LightPath™ 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

Primary study design

Interventional

Study design

Prospective randomised controlled multi-centre study

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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 LightPath™ 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

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 ^{18}F -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

United Kingdom

England

Wales

Germany

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

Llandough

United Kingdom
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
Henricistraße 92
Essen
Germany
45136

Sponsor information

Organisation
Lightpoint Medical Ltd

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

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
HRA research summary			28/06/2023	No	No
Plain English results			05/05/2022	No	Yes