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Gamma probe detection in patients undergoing a PET scan

Submission date 07/02/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/04/2014	**Overall study status** Completed	
Last Edited 07/08/2019	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Sentinel lymph node biopsy (SLNB) is the standard method used to assess the lymph nodes in the armpit in breast cancer patients when these are not palpable (felt by touch) or seen on ultrasound imaging. The gold standard for SLNB is the combined technique, using both radioactive tracer (a radioactive substance used in medical imaging) and blue dye. Technetium 99m (99mTc) is the tracer used in SLNB and is detected by a handheld device called a gamma probe. The readings from the gamma probe and/or the discolouration from the blue dye are used to find the SLNs. About 25-30% of patients undergoing SLNB will have cancer cells in the SLNs. In these patients all the lymph nodes in the armpit need to be removed a procedure known as axillary node clearance (ANC). At the moment the procedure is performed during a second operation, because there are no accurate techniques that can assess the SLN during the initial surgery. Cerenkov Luminescence Imaging (CLI) is a recently-discovered technique based on the observation that radiotracers also generate visible light. CLI allows widely available Positron Emission Tomography (PET) radiotracers, including 18F-fluorodeoxyglucose (18F-FDG), to be imaged. The uptake of 18F-FDG is generally greater in tumour tissue than in healthy tissue. This allows the cancerous tissue and non-cancerous tissue to be identified. 18F-FDG can also be detected by the gamma probe commonly used in SLNB. The gamma-probe signal from 18F-FDG may cause interference with the gamma-probe signal from 99mTc (called cross talk). This might interfere with SLNB procedure. This study has been designed to look at the amount of cross talk between the gamma-probe signal from 18F-FDG and the gamma-probe signal from 99mTc.

Who can participate?

Female patients aged 18 or over who are about to have a routine PET-scanning procedure will be invited to take part.

What does the study involve?

Participants will receive an injection of the radioisotope 18F-FDG for the PET scan. After they have been given the injection, a gamma probe will be placed in their right and then left armpit. The highest and lowest signal will be measured.

What are the possible benefits and risks of participating?

There are no direct benefits to the patient; however, participation in the study may benefit

future patients undergoing surgery for breast cancer if the technique works. There are no risks or side effects associated with this research study. The patient will not receive any drugs or undergo any invasive procedures as part of the study and the routine care will not be affected. This study is purely observational.

Where is the study run from?
St Thomas Hospital (UK)

When is the study starting and how long is it expected to run for?
February to May 2014

Who is funding the study?
King's College London (UK)

Who is the main contact?
Maarten Grootendorst
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Contact information

Type(s)
Scientific

Contact name
Mr Maarten Grootendorst

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.1 16/12/2013

Study information

Scientific Title

Gamma-probe cross talk from 18F-FDG in technetium-99m energy window

Study objectives
The cross talk information will aid in establishing the required activities (MBq) of technetium-99 and 18F-FDG to enable successful sentinel lymph node (SLN) detection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 01, 31/01/2014, ref: 14/SS/0013

Study design
Observational non-randomised study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Cancer

Interventions
This study has been designed to look at the amount of cross talk between the gamma-probe signal from 18F-FDG and the gamma-probe signal from 99mTc. Patients that are about to have a routine PET-scanning procedure will be invited to take part. They will receive an injection of the radioisotope 18F-FDG for the PET scan. After they have been given the injection, a gamma probe will be placed in their right and then left armpit. The highest and lowest signal will be measured. The study will be conducted at the clinical PET centre at St Thomas Hospital, and a maximum of 20 patients will take part in the study. There will be no further follow-up or patient contact once measurements have been obtained.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

The highest and lowest measurement detected by the gamma probe in patients injected with 18F-FDG

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/02/2014

Completion date
15/05/2014

Eligibility

Key inclusion criteria
1. Female patients ≥ 18 years of age who are willing to participate in the study and who provide written informed consent
2. Patients receiving an intravenous 18F-FDG injection for a diagnostic PET-scan as part of routine care

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
Patients with high 18F-FDG uptake in the thoracic or axillary region. The PET-report will be reviewed the day after the PET-scan to identify these patients. Hence, these patients will be excluded retrospectively.

Date of first enrolment
15/02/2014

Date of final enrolment
15/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
London
United Kingdom
Se1 9RT

Sponsor information

Organisation
King's College London - Guy's and St.Thomas' Foundation Trust (UK)

Sponsor details
Room 1.8 Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 1UL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King’s College London

Alternative Name(s)
Collegium Regale Londiniense, King's, KCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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?
Results article	results	01/06/2017	07/08/2019	Yes	No
HRA research summary			28/06/2023	No	No