

Gamma probe detection in patients undergoing a PET scan

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

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

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Additional identifiers

Protocol serial number
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

Primary study design

Observational

Study design

Observational non-randomised study

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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 ^{18}F -FDG injection for a diagnostic PET-scan as part of routine care

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Total final enrolment

20

Key exclusion criteria

Patients with high ^{18}F -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**

United Kingdom

England

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)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

University/education

Funder Name

King's College London

Alternative Name(s)

King's, Collegium Regium apud Londinenses, Collegium Regale Londinense, Collegium Regale Londiniense, KCL

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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