

# Gamma probe detection in patients undergoing a PET scan

<b>Submission date</b> 07/02/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/04/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/08/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> 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  
maarten.grootendorst@kcl.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Maarten Grootendorst

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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

**Study design**

Observational non-randomised study

**Primary study design**

Observational

**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  $\geq 18$  years of age who are willing to participate in the study and who provide written informed consent
2. Patients receiving an intravenous  $^{18}\text{F}$ -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  $^{18}\text{F}$ -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?
<a href="#">Results article</a>	results	01/06/2017	07/08/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes