NHS Grampian

**Oncology Department, Clinic D**
**Aberdeen Royal Infirmary**
**Aberdeen AB25 2ZD**

# Detection of hypoxia in Lung carcinoma

## Patient Information Sheet

You are being invited to take part in a research study. Before you decide whether or not to accept our invitation it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Feel free to ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part. Thank you for reading this.

### What is the purpose of this imaging study?

This imaging study will examine whether we can improve the care of patients with lung cancer by using a new types of PET/CT scan called FAZA-PET. Researchers are trying to develop good methods to detect tumour cells that are hypoxic (contain low oxygen levels), as they are less likely to be killed by anti-cancer drugs or radiotherapy. We think that PET scans may be a reliable non-invasive method of obtaining this information. The FAZA refers to the radioactive tracer that is used to provide information about your tumour. This is injected into the patient who then undergoes a special CT scan.

In order to find out if these scans can reliably detect low oxygen levels in tumours, we need to carry out this clinical study. We are asking patients if they will undergo two PET/CT scans prior to their planned treatment. The scans will enable us to assess the oxygen levels in patients' tumours. The scans will be separated by a short period of two to seven days. This will allow us to check how reliable the PET/CT scan test is by comparing the two scans with each other to see if they provide the same information.

### Why have I been chosen?

You have been chosen because you have had a diagnosis of lung cancer and are well enough to undergo two PET/CT scans prior to your treatment for your lung cancer. If you accept our invitation, you will be one of 10 lung cancer patients who will take part in the study. You will undergo two PET/CT scans using FAZA tracer. Because you are due to undergo surgery following the PET/CT scans, we will also study the sample of tissue provided to gain further information about the oxygen levels in the tumour. Three additional

laboratory tests will be performed on the sample obtained from your surgical procedure. No additional surgical samples will be required.

**What is a PET/CT scan?**

A PET/CT scanner combines two types of imaging: Positron Emission Tomography (PET) and X-ray computed tomography (CT). The PET scan looks at how well the body is working, while the CT scan provides information about the body's anatomy such as size, shape and location of organs. By combining the two, a PET/CT scan allows physicians to more accurately diagnose and identify cancer, heart disease and brain disorders.

**How is the scan carried out?**

We will give you a small injection in your arm or back of your hand. After the injection you are required to rest on a couch in the department for up to 2 hours before the scan begins. During the scan you will feel no pain or unusual sensation of any kind. Please try to wear loose comfortable clothing with no metal if possible (e.g. tracksuit).

You will be made comfortable on a bed that slides into the scanner to a position near to the part of your body being examined. You must remain as still as possible during the scan. When you are having the scan you will be able to contact the staff at any time – they will be in the room adjacent and watching through a special glass window and with a close-circuit TV to make sure that you are comfortable.

**How long does it take?**

The scan will take 15 - 25 minutes. You will not be required to keep still for all of this time. You will have to rest for between 2-3 hours after the injection before your scan can start. This is to allow the tracer to spread evenly through your body. You will be able to stop the scan at any time if you feel uncomfortable (e.g. if you experience claustrophobia).

**When will I have my scans?**

The PET scan will be organised by your doctors to ensure that they fit with your planned treatment. The PET scans will be done in the week before you undergo surgery to remove the tumour.

**Are there any after-effects from the scan?**

You should feel no ill effects from the injection. The radiotracer that will be injected has already been safely tested in many patients, and is not associated with toxicity or any known side-effects. It does not make you sleepy or prevent you from driving. As the injection is mildly radioactive we recommend that you drink more fluids than usual for the rest of the day to help to wash it out of your body. The examination does involve a moderate radiation dose (maximum of 6.6 mSv). This is the same as a person would experience as background radiation over a 5 year period, due to naturally occurring radioactivity in the environment. Because of the radioactive injection, we ask you to avoid close contact with young children, babies or pregnant women for approximately 8 hours after you leave. This means not having a child sitting next to you or on your knee for more than 30 minutes, to avoid exposing them to unnecessary radiation.

**Do I have to take part?**

No. It is up to you to decide whether to take part. If you do decide to take part, please fill out the reply slip or contact the study team as outlined in the cover letter. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You will also be given a copy of the consent form for your records If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

**What will happen to me if I take part?**

If you decide to take part in the study the research team will discuss the study with you and identify suitable times for you to have your PET/CT scans. This will not delay your surgery or the start of your treatment. After each PET/CT scan has been carried out the results of your scan will be shared with researchers, who will compare the PET/CT scan data.

Three additional laboratory tests will be performed on the sample obtained from your planned surgical procedure. No additional surgical samples will be required. These samples will provide additional information about your tumour and be compared to the results of the PET/CT scans. Your consent will be obtained in order for us to conduct these additional laboratory tests.

Following your surgery, you will undergo a period of follow up with the medical team involved in your care and will be asked to attend routine follow up clinic appointments. The data from these follow up appointments will be recorded as part of the study.

Occasionally, a scan may provide incidental findings about your condition. If this occurs the relevant information will be discussed with yourself, and with your GP and/or consultant as appropriate, to assist with your medical management

**Will my travel expenses be reimbursed?**

Yes, travel expenses for the study visits will be reimbursed, up to a total of £20. If you decide to participate in the study, the study team will provide you with the paperwork to reclaim travel expenses incurred.

**What are the possible benefits of taking part?**

There may be no direct benefit to you in taking part in this study. However, we hope that the results of our investigation will help to improve the quality of care for patients diagnosed with lung cancer in the future.

**Will my taking part in this study be kept confidential?**

All information, which is collected, about you during the course of the research will be kept strictly confidential. Data will be anonymised and stored securely to ensure confidentiality is preserved. Only individuals with direct involvement in the study will have access to the data.

**What will happen to the results of the research study?**

The results we obtain will form the basis of a final report that will be available for participants and which may be published in a scientific journal. Participants will be provided with a condensed summary of the results and will have access to the full report if they wish to receive a copy.

**Who has reviewed the study?**

The study has been reviewed and approved by the North of Scotland Research Ethics Committee.

**What if there is a problem?**

At any time during the study, if you have a complaint or a concern that you have been unable to resolve with the Principal Investigator, Kirsten Laws, you may contact Leslie Samuel, who is a consultant oncologist but is not directly involved in this research study. Contact details for both Dr Laws and Dr Samuel are provided below. You can also contact the NHS Grampian Feedback Service at any time, details provided below.

As a patient of the NHS, if you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms would be available to you

**Contact for Further Information**

If you require any further information, please feel free to contact the following people:

Dr Kirsten Laws, Clinical Research Fellow
Office 3.23, Institute of Medical Sciences, University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD
Email: kirstenlaws@nhs.net
Telephone: 03454566000 (ask for Dr Kirsten Laws) or 07961520560

**Alternative Contact for the study**

Dr Leslie Samuel
Consultant Clinical Oncologist
Department of Medical Oncology
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
AB25 2ZD
Tel: 01224 551273

**NHS Grampian Feedback Service Contact Details**

NHS Grampian Feedback Service
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE
Tel: 03453376338
Email: nhsgrampian.feedback@nhs.net

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