Imperial College London

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Patient Information Sheet

Multinational Anal Squamous Cell Carcinoma: Registry and Audit

IRAS: 335443

Invitation

We have created a research database for patients with Anal Squamous Cell Carcinoma (SCC) and Anal squamous intraepithelial lesions (SIL). We would like to invite you to take part. We want to emphasise that this is entirely voluntary, and your decision will not affect your care in any way. Before you decide, 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 decide whether you would like to take part. Thank you for reading this.

What are Anal Squamous Intraepithelial Lesions and Anal Squamous Cell Carcinoma?

An anal SIL is a pre-cancerous change to cells around the anus that can cause an increased risk in developing Anal Squamous Cell Carcinoma (anal cancer). It is related to a previous infection with Human papillomavirus (HPV). We have observed that SIL can progress over time to Anal Squamous Cell Carcinoma, but little is known about the rate of progression, risk factors and genetic changes that allow this to happen. Not every patient with SIL develops anal cancer; the reasons for this are unknown.

What is the purpose of the study?

We created an international database of patients with anal cancer or high-grade SIL (HSIL). We create databases of rare cancers such as Anal Squamous Cell Carcinomas so that we can study them in greater depth in larger patient numbers. It is difficult for us to produce high quality research for rare cancers unless we can recruit and study many patients. As Anal Squamous Cell Carcinoma is rare, it is difficult to study in large numbers unless research teams collaborate with each other. We hope that including your data, along with other patients, as well as collaborating with other research teams internationally that we may be able to answer important research questions and improve care.

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If you agree to take part, your clinical data will be submitted into the database, but only your local clinical team will be able to see your personal data. Anyone else accessing the database will not be able to personally identify you as your data will be held anonymously.

Why am I being invited to take part?

You have been invited to take part because you have recently been diagnosed with Anal Squamous Cell Carcinoma or a high-grade squamous intraepithelial lesion.

Do I have to take part?

It is up to you whether you decide to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. 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.

If you agree to take part, we will review your patient case notes from [Enter Trust Name] and request access to your notes from the Sexual Health database if you have previously had high resolution anoscopy screening. Your data will then be collected, anonymised and included in our study.

If during the research, you wish to opt out of the study or have your data deleted, we will identify your data and remove it. It is possible that your data at the time of your request may already be downloaded to be analysed. Once analysis is underway your data will be anonymous and impossible to identify therefore we will be unable to exclude you from research that is already started. For research that has not yet started we will, on your request, remove your data.

Your anonymised data will only be used in a manner approved by the Research Ethics Committee.

If you decide to take part, we will ask you to sign a consent form. All the information which is collected about you during the research will be kept strictly confidential. Any

information about you which leaves the hospital will be fully anonymised. All research activities will use anonymised data only.

What data will be collected?

We will collect demographic information such as age and gender. We will also collect information about your medical conditions and medications. If you are HIV positive, will also collect your last viral load and CD4 counts. If you have attended screening for anal SIL, we will collect information about this and any previous treatment for SIL that you have received. If you have Anal Squamous Cell Carcinoma, we will collect data on which treatments you receive and the pathological staging of your cancer. We will also include long term follow up outcomes such as a new diagnosis of Anal Squamous Cell Carcinoma or disease recurrence as well as survival outcomes.

What are the possible disadvantages and risks of taking part?

There are no additional risks in taking part and your decision about deciding to take part will not affect your ongoing care.

What are the possible benefits of taking part?

The information gained will help us to better understand the progression of SIL and the treatment of anal cancer and we hope will help us to identify patients with SIL at the highest risk of developing anal cancer in the future. There will not be any immediate benefit to you in taking part. We hope however that this research could benefit patients being treated for anal cancer in the future.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigators [Insert

contact details of local investigator]. The normal National Health Service complaints mechanisms are also available to you, please contact the Trust's Patient Advice Liaison Service (PALS) on *[insert contact details].* If you are still not satisfied with the response, you may contact the Imperial AHSC Research Governance and Integrity Team.

Will my taking part in this study be kept confidential?

All information which is collected about you during the research will be kept strictly confidential. The data will be collected shortly after you have given your consent to be included in the study. Any information about you which leaves the hospital will be anonymised so that you cannot be recognised from it. Your data will only be accessible and personally identifiable by members of your direct health care team in the way this information sheet has described. The database will be hosted by an external IT contractor who specialises in maintaining clinical databases. The external contractor will be held to these same confidentiality standards.

An explanation on data collected from patients diagnosed with anal cancer or HSIL before the REC approval date

Since anal cancer is a rare cancer, it is difficult to collect data from large numbers of patients in order to carry out high quality research. This has a negative impact on research and medical advancement around the condition.

Most hospitals will have at most 10 new cases of anal cancer per year, therefore making data collection, medical research and innovation slow.

For this reason hospitals have permission to enter their historical anal cancer data into the database without requesting consent from their historical patients. These patients are defined as patients diagnosed with anal HSIL and/or cancer before the REC approval date [15/01/2024]. Anyone diagnosed with anal HSIL and/or cancer after this date will need to be consented. This is in an attempt to maximise the amount of data collected in the database in order to produce higher quality research on anal cancer.

If you have further questions about this then please contact us (see contact information below).

What will happen to the results of the research study?

Results will be collated and analysed. Data from this study will be presented at national or international conferences and written up for publication. Our results may be used to support other ethically approved research on the topic of anal HSIL and cancer in the future and may be shared anonymously with other researchers worldwide. If you would like a summary of the results when available, please inform the doctor/ investigator.

Who is organising and funding the research?

This project is registered with Imperial College London. The Red Trouser Day Charity is funding this research. None of the team members are receiving any financial incentives for conducting this research.

Who has reviewed the study?

The **East Midlands - Derby Research Ethics Committee** has reviewed this study and given their approval. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

Contact for Further Information

If you have any further questions, please contact: [Insert contact details of local investigator]

Please note that the Privacy notice will be provided alongside this Patient information Sheet.

Thank you for considering taking part in this study and should you decide to take part, you will be given a copy of the information sheet and a signed consent form to keep.

Date given to the patient _____