[On local headed notepaper]

OASIS Study

(ObservAtional study to investigate Surgical site Infection in ulcerated Skin cancers)

Patient Information Leaflet

A large-print version of this sheet is available on request.

We invite you to take part in a research study. Please read the following information and discuss it with family or friends if you wish. This leaflet will help you understand why the research is being done and what it means for you if you decide to take part.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information on the conduct of the study.

Please take time to decide whether or not you wish to take part.

A doctor or nurse will also talk to you about the study and can answer any questions.

How to contact us

If you have any further questions about this study, please talk to

Rachel Abbott rachel.abbott@wales.nhs.uk

Stela Ziaj stela.ziaj@ouh.nhs.uk

Thank you for reading this information sheet.

Part 1: Purpose of the study and what will happen to you if you take part

What is the purpose of the study?

The aim of this study is trying to find out if patients with ulcerated skin cancers (skin cancer where the overlying skin is broken) have an increased risk of skin infections following surgery.

People with ulcerated skin cancers requiring surgical removal will be invited to participate in the study. We will not change anything that your surgeon or dermatologist usually does. We will observe and document what happens as part of your routine care. This will help us to plan further studies in the future.

Why have I been invited?

Your dermatologist or surgeon has diagnosed you with possibly having a skin cancer with ulceration that needs removing by surgery.

Do I have to take part?

No. Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide. We will describe the study to you and go through this information sheet.

If you agree to take part you will be asked to sign the consent form at the end of this leaflet to show that you have agreed to take part. You will be given a copy of this information sheet and a copy of the consent form to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What will happen to me if I take part in the study?

In this study we are observing whether you develop a skin infection following surgery. We will also collect data to help design future studies in this area. We are not asking your dermatologist or surgeon to change their usual practice and your care remains the same as for any other patient. However, participants at the University Hospital of Wales will have a swab taken of the ulcerated skin cancer.

If you agree to take part in the study you will be asked for your consent and we provide you with all the relevant information. At the time of surgery, we will collect information about you, the skin tumour type, your procedure and whether antibiotic tablets were prescribed. Participants at the University

Hospital of Wales only will have a skin swab taken from the ulcer. Everyone will receive 'normal clinical care' thereafter.

If your wound becomes red or painful or smelly or starts leaking fluid or fails to heal after the stitches are removed then you may have a wound infection. If you are concerned then you should seek medical advice to investigate your symptoms and for appropriate treatment. In the first instance please contact your local dermatology department – contact details are available on your 'wound care advice' sheet. If the department is closed then contact your GP or attend A&E.

If you are diagnosed with a wound infection then you will be asked to take a 'wound selfie' ie. a photo of your wound on your camera/ phone. Please include the whole of the wound in the photo and ensure that it is in focus. Please avoid including any facial features or personal information appearing in the background that could potentially identify you or your location. When you have taken the photo then please e-mail it to the Cardiff University Centre for Trials Research (CU CTR) who are co-ordinating this study: CTR-OASIS@cardiff.ac.uk

If you are not able to take of photo of the wound then you can attend the department to have a photograph taken by a medical photographer. Please speak to staff at your local dermatology department for further details.

The research team from CU CTR will arrange to contact you four weeks after the surgery with a questionnaire via post or e-mail depending on your preference. The questionnaire will determine whether you had any concerns about post-operative infection and what action was taken. Please be aware that the photo will not be seen by your local healthcare providers and so if you do have any concerns about infection then you should contact your local healthcare providers.

Will I get any expenses?

There are no travel expenses available for this study. If you develop a wound infection and you are not able to take a photo and send it to CU CTR then you are welcome to attend medical photography to have a photo taken however this is not compulsory.

Are there any side effects or disadvantages of taking part in this study?

There will be no side effects as we are not changing the treatment your doctor gives you, we are simply recording if a infection develops or not and the type of infection and organism which caused it. The care that you will receive will be the same as the care that you would receive if you were not taking part in the study. You will be closely monitored as part of your usual care.

Are there any benefits to taking part in this study?
You will be helping us plan a future study into whether the use of antibiotics in patients with ulcerated skin cancer would be beneficial following surgery. You may not directly benefit from this study; however, information we get from the study could help future care for patients with ulcerated skin tumours and improve their post operative outcomes.

Will my taking part be kept confidential?
Yes. All information which is collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice in accordance with the General Data Protection Regulations and all information about you will be handled in confidence. Please refer to part 2 for further details.

Involvement of your General Practitioner (GP) or other Healthcare Practitioner
Your GP will not be informed that you are participating in this study because it is an observational study. Your Dermatologist will know that you are taking part in the study.

This completes Part 1 of the information sheet. If the information in part 1 has interested you and you are considering participation, please continue to read the additional information in part 2 before making any decision.

Part 2: More detailed information on the conduct of the study

What will happen if I don't want to carry on with the study?
Taking part in this study is entirely voluntary and you are free to change your mind at any point during or following completion of the study without giving a reason. A decision to withdraw at any time will not affect the standard of care you receive, nor will it affect your relationship with the medical and nursing team who are looking after you.

If you withdraw from the study, we will withdraw all your data including any wound photos and we will not use any of your data in the study analysis. However, you cannot withdraw your data after it has been anonymised for analysis.

If you do not send back the completed questionnaire then we will make three attempts to telephone or text you to remind you to send back the questionnaire. If we are unable to contact you by telephone then we will write to you to ask you to contact the study centre.

What if something goes wrong?
If you have a concern about any aspect of this study, you should speak with your healthcare practitioner or other healthcare professional who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, in England you can do this through the Patient Advice and Liaison Service (PALS) who provide advice and support to patients, their families and their carers; website: http://www.nhs.uk. The contact number of Oxford University Hospitals PALS is 01865 221473. The contact number of Birmingham University Hospitals PALS is 0121 371 3280. In Wales, you can do this through the NHS Complaints Procedure via the Patient Concerns Service (Wales) [Concerns Department, Cardiff and Vale University Health Board Headquarters, University Hospital of Wales, Heath Park, Cardiff CF14 7XB, telephone 02920742202].

In the unlikely event that you think you have been harmed by taking part in this study there are no additional compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part be kept confidential?Yes. Cardiff and Vale UHB is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information when we receive the content and for using it properly. However, we are not responsible for looking after your data when it is in transit or for any photos taken for this study which are stored on your camera or phone.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

Cardiff and Vale UHB will keep identifiable information about you for 5 years after the study has finished. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting cav.ig.dept@wales.nhs.uk.

Further information on Cardiff and Vale UHB's Privacy Policy is available here:

http://www.cardiffandvaleuhb.wales.nhs.uk/privacy-policy

You can also raise any concerns about the use of your data with the Information Commissioner's Office (www.ico.org.uk).

[University Hospital of Wales (UHW)/Oxford University Hospital NHS Foundation Trust/ University Hospitals Birmingham NHS Foundation Trust] will collect information from you for this research study in accordance with our instructions. Individuals from [Oxford University Hospital NHS Foundation Trust/ University Hospitals Birmingham NHS Foundation Trust], Cardiff and Vale University Health Board and regulatory organisations may look at your medical and research records to check the accuracy of the research study. This information will be kept in a secure place in each recruiting site.

You will be allocated a study number which will be used to identify you on study documents. [University Hospital of Wales (UHW)/Oxford University Hospital NHS Foundation Trust/ University Hospitals Birmingham NHS Foundation Trust] will pass the information collected from you, including your name, address or e-mail address, and phone number, to CU CTR. Electronic transfer of this data to CU CTR will be encrypted. The study data will be entered onto an excel spreadsheet which is stored on a private network protected by a firewall and password protected.

The only people in CU CTR who will have access to information that identifies you will be people who need to contact you to send and receive your questionnaire +/- 'wound selfie' or audit the data collection process. Your phone number may be used to remind you to complete your questionnaire. The people who analyse the information will not be able to identify you and will not be able to find out your name or address or phone number. CU CTR will destroy identifiable information about you after the study has finished. [University Hospital of Wales (UHW)/Oxford University Hospital NHS Foundation Trust/ University Hospitals Birmingham NHS Foundation Trust] will keep identifiable information about you from this study 5 years after the study has finished.

After the study has finished then anonymous information may be shared with other researchers to ensure that research is open to peer scrutiny, to optimise the use of good quality research data and to support policy and other decision-making.

Who has organised and sponsored the research?
The OASIS observational study is funded by the UK Dermatology Clinical Trials

Network (UKDCTN) and is being organised by CU CTR. Cardiff and Vale University Health Board is the study Sponsor.

What happens to the results of this study?
The results will be entered into an Excel spreadsheet and then analysed anonymously by the study research team. When the study is complete the results may be published in a medical journal or presented at local, national or international meetings. No individual participants will be identified. If you would like to obtain a copy of the published results, please ask your doctor.

Who has reviewed the study?
This study has been reviewed by the UK Dermatology Clinical Trials Network (UKDCTN) before funding was given. All research in the NHS is looked at and reviewed by an independent group of people called a Research Ethics Committee. This committee exists to protect the safety, rights, wellbeing and dignity of patients. This study has been reviewed and given favourable opinion by the South Central-Hampshire B Ethics Research Committee.

Further information and contact details

If you would like more information about this study here are the contact details of your local Research team;

Cardiff and Vale University Health Board:
Dr *Rachel Abbott* Email: rachel.abbott@wales.nhs.uk
Oxford University Hospital NHS Foundation Trust:
Dr Rubeta Matin Email: rubeta.matin@ouh.nhs.uk
University Hospitals Birmingham NHS Foundation Trust:
Dr Agustin Martin-Clavijo Email: agustin.martin-clavijo@uhb.nhs.uk

If you have any general queries about participating in research you can contact the Patient Advisory and Liaison Service (PALS) in England or the Patient Concerns Service in Wales

If you would like more information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations in the UK) have published a booklet entitled 'Understanding Clinical Trials'. For a copy contact UKCRC: Tel: 0207 670 5452 or visit their website www.ukcrc.org