

PATIENT INFORMATION SHEET 2

(4th March 2008: Version 2)

IMPROVING CHRONIC WOUND HEALING WITH INTELLIGENT DRESSINGS

Study number:.....

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You are being invited to take part in the above research study. 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 discuss it with others if you wish. We will be happy to clarify anything that is not clear.

- **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 about the conduct of the study. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

We are currently attempting to improve the management of patients with chronic leg wounds. We know that bacteria (which are normally present on your skin) play a role in stopping the normal healing process in chronic wounds. To help treat your wound quickly and effectively if it gets infected, this project is developing an "intelligent wound dressing" to count and identify wound bacteria rapidly whilst you wait in the clinic. Doctors usually have to wait several days for such results if swabs are sent to the laboratory. We need to test a prototype dressing and its various components in a more clinically relevant environment. Hence, the need for clinical samples from various wounds.

Why have I been chosen?

We are asking patients who are about to undergo mastectomy surgery to donate wound fluid collected in their wound drains to this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. A short questionnaire also needs to be completed.

You are free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive. If you decide to take part you are still free to withdraw at any time without giving a reason.

Withdrawal will not affect any further treatment. However, your data collected up to the date of withdrawal may be used anonymously for final analysis and/or presentation.

What will happen to me if I take part?

We are asking mastectomy patients to donate mastectomy drain fluid after surgery. This fluid is routinely collected from your wound and then normally discarded. Hence, this procedure is not experimental. If you are willing to give mastectomy drain fluid, instead of discarding the fluid that has been collected from your drain, it will be saved and used for research.

No normal treatment will be withheld for any part of the study. There will also be no long-term monitoring or follow-up from this study.

What do I have to do?

If you have agreed to donate mastectomy drain fluid, this will be collected through the normal wound drain that you will have in place after surgery, whilst you are in hospital. No additional clinical interventions will be done. You will also be asked a few simple questions about you and your wound. You do not need to do anything further.

What is the drug, device or procedure that is being tested?

No drugs, devices or procedures are being tested on you. We will only be taking samples from your wound to be tested later in the laboratory.

What are the alternatives for diagnosis or treatment?

None. Donating samples to this study will not affect the treatment you receive in any way.

What are the side effects of any treatment received when taking part?

None. As we are only using routine procedures to obtain your wound samples, there should be no adverse affects after any of these procedures.

What are the other possible disadvantages and risks of taking part?

None. We do not anticipate any risks out of proportion to those normally associated with the treatment of mastectomy wounds.

What are the possible benefits of taking part?

Future benefits will be the more rapid detection of bacteria in wounds leading to quicker administration of appropriate antibiotics.

What if there is a problem?

You can contact any member of the research team if you are concerned or develop any problems (contact details are listed at the end).

Will my taking part in the study be kept confidential?

Yes. All information that is collected about you will be kept strictly confidential during and after the study. You may be identified only by the study number in any published results and this will

not be traceable to you.

Who do I contact for more information or in case of an emergency?

If you require any further information regarding this study please contact: Professor Patricia Price (Tel: 029 2068 2179) from the Wound Healing Research Unit or Professor David Thomas (029 2074 3504) and Dr Katja Hill (029 2074 4252) from the Dental School.

In case of a medical emergency, it may be safest to contact your consultant or GP.

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

What will happen if I don't want to carry on with the study?

If you withdraw from the study, we will destroy all your identifiable samples, but we will need to use the data collected up to your withdrawal.

Will my taking part in this study be kept confidential?

Yes. You will be asked to answer a few questions on a simple questionnaire about your wound. If you are unable to answer the questions put to you, you will be asked whether medical staff (only doctors or nurses) can have access to your medical records to complete the questionnaire.

Your confidentiality will be safeguarded during and after the study by using only your initials and sample number to identify any samples. All data and samples will be securely stored

Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.

What will happen to any samples I give?

Any samples that you donate to this study will be anonymously labelled so that only your initials and sample number are on them. All samples will be transferred to the Dental School for secure storage (at -80°C) until used. Only the research staff on this project will have access to them.

Will any genetic tests be done?

No.

What will happen to the results of the research study?

It is intended that results from this study will be published in peer reviewed journals and/or at scientific conferences.

If you are interested in finding out the results, this can be arranged by contacting any member of the research team.

Who is organising and funding the research?

This study is being organised by Dr Katja Hill and Professor David Thomas (Dental School) and

Professor Patricia Price (Department of Wound Healing).

This project is being funded by the Engineering and Physical Sciences Research Council.

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS and Wound Healing Research Clinic by the South West Wales Research Ethics Committee.