

PATIENT INFORMATION SHEET

(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?

All patients with leg wounds and attending these outpatient clinics are being asked to participate in this study if they are suitable candidates. We are looking for volunteers to donate a variety of different wound samples.

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?

You will be asked which parts of the study you are willing to participate in. From chronic leg wound patients we are asking for discarded wound dressings, debrided wound material, wound imprints, wound fluid and wound swab donation. All procedures (except chronic wound fluid donation) should take no longer than 5-10 minutes and will be done whilst you are having your normal appointment.

If you are willing to give chronic wound fluid, this procedure will take up to 4 hours and you will be asked to attend a separate appointment on another day at the Wound Healing Research Unit specifically for this purpose. Your travel expenses for this additional appointment will be reimbursed.

None of the procedures described below are experimental. 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.

(i) Wound swabs

Your wound will be washed briefly in sterile saline and then a sterile swab will be rubbed gently over the wound surface. This should take no longer than 2-3 minutes. The swab will be sent to the laboratory for microbiological culture. This is a routine procedure for determining which bacteria are present in your wound. You may have had one of these before.

(ii) Discarded wound dressings

When your old dressing is removed during your appointment, you will be asked whether you are willing to donate it to the study. If you donate a discarded wound dressing, you will also be asked to give a wound swab (as described above) so that we can culture the bacteria in your leg wound at the same time for comparison.

(iii) Debrided wound material

If you are having dead wound material removed from your wound during your clinic visit as part of your normal treatment, you will be asked if you are willing to donate it to this study. If you donate this debrided wound material, you will also be asked to give a wound swab (as described above) so that we can culture the bacteria in your leg wound at the same time for comparison.

(iv) Wound imprints

Your wound will be washed briefly in sterile saline and then a clean dressing will be placed over your wound and left in place for up to 10 minutes. This "imprint" of your wound will then be donated to the study. If you donate a wound imprint, you will also be asked to give a wound swab (as described above) so that we can culture the bacteria in your leg wound at the same time for comparison.

(v) Chronic Wound fluid

If you are willing to give chronic wound fluid, you will be given a separate appointment as this procedure can take up to 4 hours depending on how wet your leg wound is. Your wound will

be washed briefly in sterile saline and then a clean dressing will be placed over it to absorb fluid from your wound. A covering dressing will be placed on top for protection. You will then be asked to rest until the dressing becomes moist and wet. At the same time as donating wound fluid, you will be asked to give a wound swab (as described above) so that we can culture the bacteria in your leg wound for comparison.

What do I have to do?

If you have agreed to donate either discarded wound dressings, wound swabs, debrided wound material or wound imprints, this will be done now during this appointment. You will also be asked a few simple questions about you and your leg wound. You do not need to do anything further.

If you have agreed to donate chronic wound fluid, you will be given a separate appointment for this which you are asked to attend. After the fluid is taken, no additional procedures are necessary.

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 leg 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 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.

Thank you for considering taking part in this study.