Patient Information Sheet

Study Title: Laboratory observational Ex-Vivo study to investigate the sensitivity and specificity of a smart dressing to detect clinically relevant wound infection

We would like to ask if you would be happy to participate in this research study.

Before you decide, you need to understand why the research is being done and what it will involve.

Please take time to read the following information carefully.

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Short Title: EVIDEnT: Laboratory observational Ex-Vivo study to investigate the sensitivity and specificity of a smart dressing to detect clinically relevant wound infection.
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UHBristol R&D No: CH/2016/6025

What is the aim of the study?
This study aims to test whether the technology developed to detect infection in a dressing for burn wounds is effective in identifying infection.

What are the reasons for doing this study?
Burn wound infections are difficult to diagnose, but may become serious if they are not treated quickly. To diagnose an infection, dressings need to be removed from the wound, which may slow the healing process. A new dressing Smartwound™ may help to diagnose wound infection without needing to remove the dressing.

The Smartwound™ dressing changes colour in the presence of the infection causing bacteria. Laboratory studies show that the dressing does change colour in the presence of bacteria, but before it can be used in patients, we need to check whether they work with the bacteria in human wounds.

The new Smartwound™ dressing will not be tested on you. The study will use samples of burn wound fluid, called exudate or biofilm, which can be taken from wound swabs and used wound dressings when you have your dressings removed. We are gathering exudate from patients with and without wound infection to see whether the dressing changes colour in the presence of the bacteria that cause a wound infection. Dressing changes and swabs are part of the normal care routine for patients with burns.

Why am I being asked to take part?
You are being asked to take part as you have either:

⇒ a burn wound with a suspected infection requiring a dressing change
⇒ a burn wound without suspected infection that requires a dressing change at least 48 hours post injury (control group)

The control group are patients who have a burn injury but have no signs of an infected wound. We need samples from both of these groups to make sure the 'smart' dressing technology is working properly.

Do I have to take part?
No, it's up to you. We will describe the study and go through this information sheet. If you decide to take part, you will be asked to sign a consent form. If you decide not to take part you don't need to give a reason and your care will not be affected.

Are there any risks to me for taking part?
There are no risks to you taking part as your dressings would normally be discarded as clinical waste, and the exudate taken with gauze/ swabs is a waste product that would normally be cleaned away during a standard dressing change.
Your samples will not be used for any other purpose and will be destroyed once they have been tested.

What happens if I take part?
We would like to collect your old standard dressings and some samples of your burn wound exudate/biofilm (burn fluid) using gauze and two cotton swabs.



The samples of exudate will be taken from you during routine treatment. This may be when you are in theatre or in the treatment area, when the wound is being cleaned.
The new Smartwound™ dressing will not be tested on you. The exudate samples will be used to test the Smartwound™ dressing in the laboratory. We would like to be able to use the medical information that the nurses and doctors write in your notes. Lastly, we would like to follow you up at 14- 21 days to ask some questions about antibiotic treatment, dressings, additional medical help and the healing of your burn wound. This would be either at one of your scheduled clinic appointments as part of normal care, or by telephone.

If you are in the control group of patients who do not have a wound infection, but later you develop signs of an infection, you may be asked if you would be happy to sign another consent form, allowing us to collect your dressings and take swab samples for a second time.

What are the benefits?
Taking part in the study will not directly benefit you. However by being able to test your wound exudate it will enable us to gain a better understanding of burn wound infection and allow further development of the Smartwound™ dressing.

What are the disadvantages?
You will have to allow for a little extra time during your planned clinic visit or be available to answer some questions about your burn wound over the telephone in the follow up stage.

Is the study confidential?
Yes, all the information you give us will be kept strictly confidential and will be used only for the purposes of this study. Data will be stored securely in locked offices and on password protected computers in a way which makes it impossible to link to you except by very few members of the research team based in the hospital. All of the samples will be anonymised with a unique study identification number.

What will happen to my samples?
They will be securely stored in a locked research fridge, labelled with your unique study number. They will then be transferred to the University of Bath and the University of Brighton, where they will be securely stored and analysed before being discarded.

What if I change my mind and want to withdraw?
Taking part is voluntary and you are free to leave the study at any time, without giving a reason, and without your medical care or your legal rights being affected. However, as samples are non-identifiable once sent for testing they will not be able to be removed from the study.

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What will happen to the results of the study?
You will be informed of the study results by letter. Results will be shared with other healthcare staff and patients as reports in medical and healthcare journals, newsletters, and talking about the results at conferences.

Who is funding and organising the study?
The trial has been funded by the Medical Research Council and is being lead by Dr Amber Young.

Who has reviewed the study?
This study has been given a favourable opinion for conduct in the NHS by the South West Cornwall and Plymouth Research Ethics Committee and local hospital research departments. The patient information leaflets have been reviewed by a public patient involvement group.

How do I make a complaint?
If you have any concerns with any aspect of this study, you should ask to speak to the doctor or nurse who is looking after you who will put you in contact with the research team. If you remain unhappy and wish to complain formally, you can do so through your local Patient Advice and Liaison Service (PALS). Details are on the NHS Choices website, www.nhs.uk

If there is anything you do not understand or if you would like more information, please speak to your nurse or contact The Burns Research Team

Thank you for taking the time to read this leaflet

The Burns Collective
Leading Children's Burns Research
A Scar Free Foundation Initiative

University Hospitals Bristol NHS
NHS Foundation Trust

UNIVERSITY OF BATH

Queen Victoria Hospital NHS
NHS Foundation Trust

University of Brighton

North Bristol NHS
NHS Trust

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