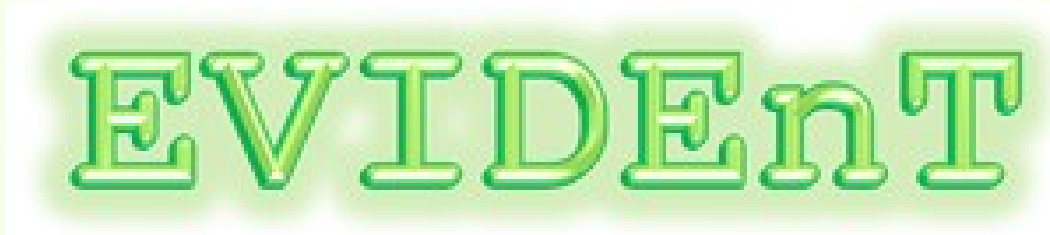


Child/Young Person Information

10-16 year olds



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

This leaflet will explain why the study is being done and what will happen if you take part.

Talk about it with your family, doctor or nurse if you would like.

Version Number: 2.2

Date: 30/09/2016

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

IRAS number: 206022

Ethics Reference Number: 16/SW/0238

UHBristol R&D No: CH/2016/6025

What is the study for?

This study is to test a new burns dressing (Smartwound™) that has been made to change colour to show the doctors and nurses if there is an infection in a burn.

The new dressing will not be tested on you.

The fluid found in your old standard dressings will be used to test the new dressing in the lab.

What are the reasons for doing this study?

If someone gets an infection in their burn it can make them very unwell. To find out if someone has an infection, their burn dressing needs to be taken off so the doctors can see the burn and swabs need to be taken for testing. Antibiotic medicines can be used to fight the infection.

The new Smartwound™ dressing may help to find burn infection without needing to take dressings off to check the burn first. Sometimes dressings are to be taken off to check burns for infection because someone feels unwell, but there isn't actually an infection in their burn, hopefully the Smartwound™ dressing will help to stop this from happening.

So far the dressing has been tested in the university laboratory and it will change colour when there is infection, but before we can use it on real burns we need make sure it always works how it should.

Why ask me?

We are asking all children/young people with

- ⇒ a burn with an infection that needs a dressing change
- ⇒ a burn without an infection that needs a dressing change (at 2 days after their burn happened or more)

Because we need both of these groups to make sure the Smartwound™ dressing is working properly.

Do I have to take part?

No, it's up to you. We will describe the study and go through this leaflet and then if you would like to take part, you will be asked to sign a form. If you don't want to take part you don't need to give a reason and your hospital care will stay the same.

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What happens if I take part?

The new dressing will not be tested on you.

We would collect your old dressings and some samples of burn fluid using gauze and two swabs and send these to two university labs. They use the fluid from these to test the Smartwound™ dressing in the lab.



This will be done at the time of your normal dressing change and where your dressing is normally changed (theatre or on the ward/clinic).

Also we would like to be able to use the information that the nurses and doctors write in your notes.

Then we would like to ask you and your family some questions about the healing of your burn, antibiotics, dressings and visits to other hospitals or clinics at 14- 21 days after you decide to take part. This could be at one of your clinic visits, in hospital, or by phone.

If you are in the group of people who didn't have an infection, but your wound later starts to show signs of an infection, you may be asked again if we could take some more of your used dressings and some swabs from you.

Why would it be good for me to take part?

You won't be able to use the new dressing on your own burns, but you will be helping others with burns in the future, by allowing us to get a better understanding of burn wound infection.

Will anything bad happen because of the study?

No, the dressing we collect would normally go in the bin and the burn fluid we collect is normally cleaned away when we change your dressing.

What will happen to my samples?

They will be stored in a locked research fridge, before being sent to the University of Bath and the University of Brighton, where they will be used to test the Smartwound™ dressing.

What if I change my mind?

That's fine, you can say no at any time.

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Will everyone be able to see my information?

No, only the people that are working on the study will be able to see and use your information. It will be locked away safely and be labelled with a study number instead of using your name.

What will happen to what you find out?

We will send you a letter with the results and write reports in medical and healthcare newspapers and talk about what we find at meetings.

Who has checked the study?

This study has been approved by a health research committee and hospital research departments.

A group of parents and young people have checked this leaflet.

If you don't understand something about the study or have any questions you can ask your nurse

Thank you for reading this leaflet



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