TO BE PRINTED ON LOCAL HEADED PAPER

Wound Healing in Surgery for Trauma

Chief Investigator: Professor Matt Costa

PROSPECTIVE PATIENT INFORMATION SHEET

We would like to invite you to take part in a research study investigating two different types of wound dressings. Before you decide to participate in the study we would like you to understand why the research is being done and what it would involve for you. Someone from our team will go through the information sheet with you and answer any questions you have.

What is the purpose of this study?

'Major Trauma' occurs when a patient sustains serious injuries to one part of the body or injuries to several parts of the body at the same time. It is often caused by road traffic accidents or falls from height. Most patients with major trauma have injuries to their legs, and many of these require surgery to fix broken bones.

In major trauma, the rate of infection in surgical wounds can be very high. This is because there is usually extensive damage to the muscles and other tissues in the leg due to the injuries. These damaged tissues are less able to resist the bacteria which cause infections. Deep infection around the bone can cause long-term problems for the patient.

One of the factors which may reduce the risk of infection in the surgical wounds of major trauma patients is the type of dressing applied over the wound at the end of the operation. New wound dressings are being developed which may reduce the risk of infection, but these are often introduced into the NHS without formal testing in research projects.

Negative pressure wound therapy (NPWT) involves applying gentle suction through a dressing to the surface of the wound as it heals. NPWT has provided promising early results in patients with surgical wounds associated with major trauma, but there has been no formal research in the NHS to investigate whether there is a true benefit to using a NPWT dressing compared with a normal standard dressing.

The aim of this study is therefore to compare NPWT with standard dressings for patients with surgical wounds associated with major trauma to the leg.

Why have I been invited?

You have sustained a broken bone in your leg during a major trauma incident. Having surgery to repair the broken bone, makes you potentially eligible for inclusion in this study. The final decision about your eligibility will be made during surgery. In some circumstances, for instance if your wound cannot be closed at the end of the surgery, the surgeon might decide you will not be eligible after all. You will then be treated with the standard care treatment of your hospital.

We expect that over 20 hospitals across the country will be taking part in this study and we hope to recruit a minimum of 1540 patients.

What is the difference between the wound dressings?

Standard dressings involve the application of a sealed, non-stick bandage or sticking plaster over the surgical wound. *Negative-pressure wound therapy* involves the application of a very similar sealed dressing but the non-stick surface of the dressing is connected to a very small pump which will gently suck any fluid away from the surface of the wound.

Which treatment will I receive?

The treatment group you will enter, will be allocated using a computer with no information about you personally. You have the same chance to be entered in the NPWT group as in the standard dressing group. After your surgery, the research associate will be able to tell you which dressing group you were assigned to.

What will happen if I decide to take part?

If you decide you would like to be involved in the research study you will be asked to sign a consent form. Even if you decide to take part now, you are free to withdraw at any time and this will not affect the standard of care you receive.

All major trauma patients with a broken leg are followed up carefully to make sure that their break is healing and that there is no sign of infection. This will be the same for the patients involved in this research study. The only additional commitment we would ask of you would be to fill out a questionnaire on three occasions during your immediate recovery period.

After signing the consent form, we will ask you to fill out the first questionnaire. The questionnaire will ask you about how well you were able to perform certain day-to-day tasks and how you were feeling before your injury occurred. The questionnaire will take approximately 10 minutes to complete.

After discharge from the hospital, your surgeon will arrange to see you at regular intervals for routine clinical check-ups including x-rays if deemed necessary. All of the patients in the study will be invited back to their hospital for a routine x-ray approximately 6 months after their injury. Photographs of the wound will be taken at your 4-6 weeks post-operation follow-up for research purposes.

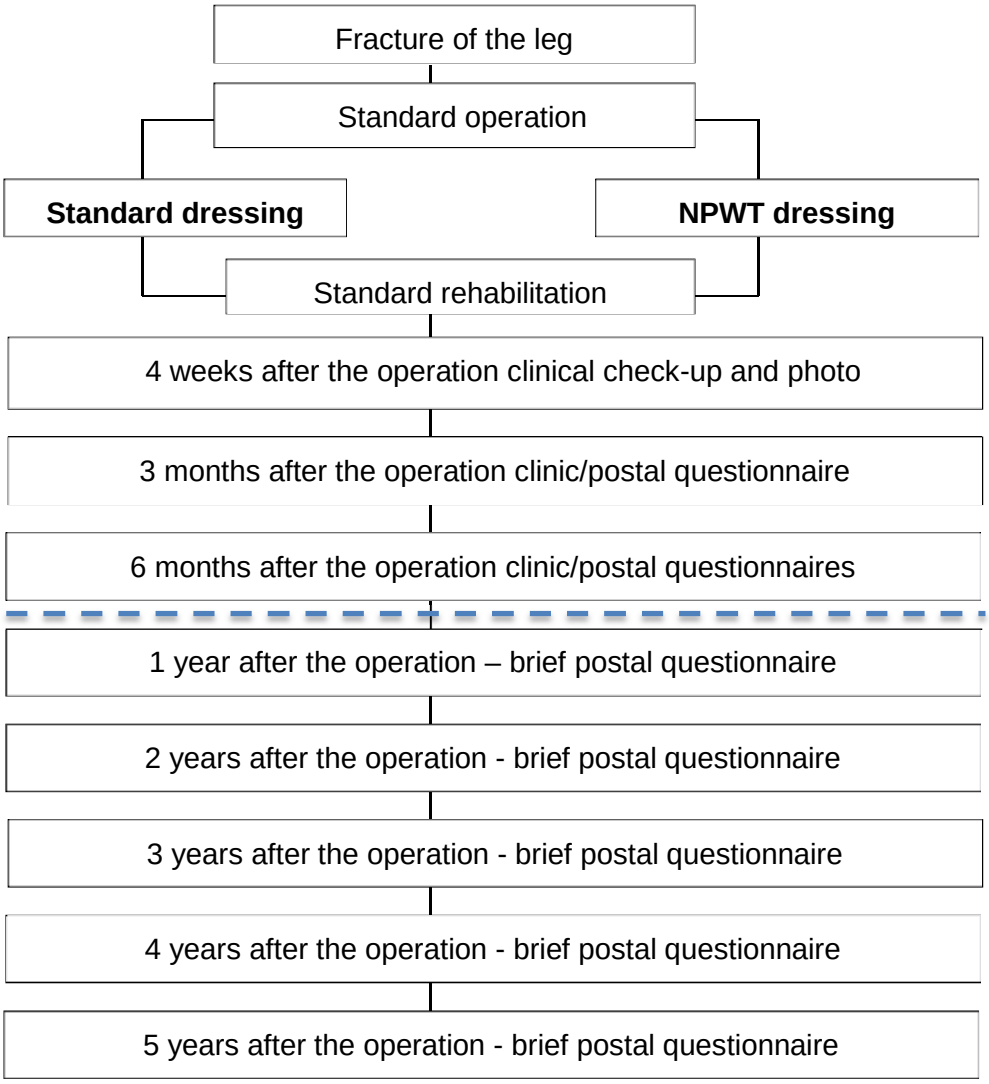
The research team will ask you to fill out a questionnaire at 3 months and 6 months after your operation. The questions will be very similar to those asked at the start of the study. The questionnaire will either be given to you when you visit the hospital for a routine check-up visit or it will be sent to you directly. If we send it out in the post, we will provide you with a stamped-addressed envelope to send it back to us once you have filled it out.

After the six month questionnaire, we will only contact you once a year with a very brief questionnaire as we are very interested in how the major trauma has affected you in the long term.

We will occasionally send you a mobile text message to inform you a questionnaire is due. We may also telephone/e-mail you and/or your alternative contact if we have not received your questionnaire, to check that we hold your current address and that you have received the questionnaire. If we have trouble contacting you during follow-up we may ask your GP or central NHS organisation to confirm your contact details.

Appropriate personal identifying information will be collected, stored and used by the University of Oxford to enable the follow up of participants in the study. A copy of the consent form will also be collected by the WHIST central trial team at the University of Oxford for monitoring purposes. Any information will be treated with the strictest security and confidentiality.

In the flow-chart on the following page you can see a schedule of the activities/assessments and what would happen after the injury.



What are the possible disadvantages and risks of taking part?

There are no specific risks of having one type of wound dressing or the other. The risks of the injury and the surgery are the same for both groups of patients in the study, and are the same as for patients who are not taking part in the study. You will have a routine X-ray taken of your broken leg before and after the operation, to evaluate the fixation and the healing process. A further routine x-ray is normally taken at 6 weeks and again at 6 months after your injury. The dose of radiation you received is equivalent to around 2 months of normal background radiation and is the same for all patients who are treated for a broken leg.

What are the possible benefits of taking part?

Both standard dressings and NPWT dressings are widely used across the NHS for patients with major trauma which includes a broken leg so there is no specific advantage to you for taking part in the study. However, the information we get from this study will help us to improve treatment for future patients with similar injuries. It will also provide valuable information on best use of resources within the NHS.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will encourage you to discuss your continued care with your doctor. If you decide to continue in the study you will be asked sign an updated consent form.

What happens if something goes wrong?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Matt Costa who is the overall lead of this trial on 01865 223114 or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG, email ctrg@admin.ox.ac.uk. NHS indemnity operates in respect of the clinical treatment with which you are provided.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Your anonymised data and personal details will be held securely and separately in access-restricted electronic databases and filing systems and only looked at by authorised members of the research team, Sponsor, regulatory bodies and participating NHS organisations when it is relevant to your participation in the study. Your information will not be released to anyone not involved in the study or used for any purpose not described here. It will not be possible to identify individual patients from any report or publication of the results of this study.
With your consent, your GP and other doctors who may treat you, but are not part of this trial will be notified that you are taking part in this trial.

What will happen to the results of the research study?

This research study is expected to last 7 years. We will publish the findings of the study at the end of the main phase (summer 2019) and at the end of the long-term follow-up (summer 2023) in medical journals and at medical conferences. If you would like to obtain a copy of the published results, please ask a member of the research team.

Who has reviewed this study?

This study has been reviewed by the *West Midlands – Coventry and Warwickshire Research Ethics Committee* and approval was given on 16 February 2016.

Contacts for further information

If, at any time, you would like further information about this research project you may contact Louise Spoors, the Trial Manager of this research study by telephoning 01865 223113. Or you can contact your local research lead <<insert name of local researcher>> telephone number <<insert telephone number>>. You can also contact Professor Matthew Costa, who is the overall lead of this study on 01865 223114.
The PALS service is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. However, PALS cannot provide information about this research trial.