Hull University Teaching Hospitals NHS Trust

… Can you help with our research study?

…Before you say yes, it's important you understand what this involves. Please read the following information carefully, discuss with others if you wish, and ask us any questions you have.

Using Thermal Cameras to Identify Infection in Orthopaedic Patients

SUMMARY

- We are investigating the use of thermal (heat) cameras to see if we can diagnose infection in adult (>18 years) orthopaedic patients.

- Although uncommon, infection can have a significant impact on patients, their families and society.

- Currently we rely on clinical assessment, X-rays, scans, and blood tests to diagnose infection. These do not always show infection early on and other conditions can sometimes mimic infection. We know that in patients who we identify infections early they do better.

- Recent research, with advancement in camera technology, has shown that thermal (heat) cameras have the potential to provide rapid and early identification of infection. However, this research is in its early stages and there has been little done in orthopaedic patients.

- Patients who agree to take part in the study will receive their normal care. If you have broken a bone (not all patients in this study will have broken a bone), you will have your ankle or wrist fixed (usually with a plate and screws) in the usual way. This study will not interfere with that. If you did not break a bone, but attended with a hot swollen joint without an injury, you may subsequently have a washout (operation) of your joint, which is standard practice, if your care team thinks this is best for you. This study will not interfere with that.

- Patients who agree to participate will be asked to fill in a consent form. At each hospital visit, in addition to normal care, patients will be asked to fill in a questionnaire and have thermal camera images taken of their affected and unaffected limbs. These will be stored for later analysis. This should take around 40 minutes.

- We usually follow up patients at around 1 or 2 weeks, 6 and 12 weeks following fixation of a broken bone. If you agree to take part in the study we will follow you up at 1 or 2 weeks, 4, 6, 12 and 24 weeks and therefore you will require two extra hospital visits. However, this will not otherwise affect your treatment and we will compensate you (£40 per extra visit) for any associated expenses.

- We usually follow up patients who have had a joint washout regularly for several months to check that there has been no return of infection. If you agree to take part in

If you have any questions about this study, or if anything is unclear, please contact the research team: Kim Dearnley (Research Nurse): Tel - 01482 674771.

the study we will follow you up during your hospital stay and at 1, 2, 4, 6, 12 and 24 weeks. It is possible you may still be in hospital for some of these visits (e.g. week 1 and 2). There will be no change in your treatment. This follow-up is similar to what would usually happen after discharge from hospital. However, you will require one extra hospital visit at 24 weeks, as this is not part of your routine care. This will not affect your treatment and we will compensate you (£40 per extra visit) for any associated expenses.

- It is completely up to you to decide if you want to take part. At any point you can change your mind. If you decline to take part your care will not be affected.

- In this study we will use information from you, your medical records and infrared photographs of your limbs. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

- Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

- At the end of the study we will save some of the data in case we need to check it or use it for future research. This will include analysing data in a future study using artificial intelligence/machine learning (advanced data science techniques). We will make sure no-one can work out who you are from the data and thermal images that are stored.

The information pack tells you about the study in more detail

INFORMATION PACK

CONTENTS OF THIS DOCUMENT

1. Why are we doing this study?

Infection in orthopaedic patients

Infection following surgery in orthopaedic patients is difficult to diagnose quickly and accurately. Once infection has taken hold it can stick to implants that we use and become very difficult to treat and patients may require further operations.

Patients who attend hospital with a red, hot swollen joint are difficult to diagnose because there are many causes, infection being just one of a long list. Without further invasive tests or scans we currently cannot tell whether or not, hot swollen joints are due to infection, gout or a flare up of arthritis or another cause. However, if infection is left without treatment this can lead to negative long-lasting consequences.

With further research we hope to identify a simpler way and quicker way to identify infection patients following surgery and patients who present to hospital with hot and swollen joints.

What is the purpose of the study?
The overall aim of the study will be to see what temperature differences can be detected using a thermal camera between the operated and non-operated side (For example: between the broken right wrist and the unbroken left wrist).

We will then understand what a normally healing broken bone looks like on a thermal image and be able to compare the temperature differences in patients who develop infection with those who do not develop infection. We will also see if there is any relationship between the thermal images and the routine blood tests we take (no extra blood will be taken).

The data will be stored securely so that an automated learning model (advanced data science techniques) can be developed to see if it can identify infection in patients early using their thermal images and blood tests.

If we can identify patients who have infection early we will be able to treat them potentially more effectively than we do now, preventing the sometimes devastating consequences (e.g. the need for joint replacement surgery) and reduce the number of operations required. This will be the first study of its kind using modern cameras.

Why have I been invited to take part?
You have been invited to take part in this study as you have either: 1) recently broken your wrist or ankle or; 2) have a hot, red joint that might be infected. You are awaiting treatment, and are suitable for this study. The surgeon looking after you is an expert in treating these problems.

2. What would taking part involve?

We would encourage you to take your time to consider your enrolment.

After reading this and discussing any questions you have, if you decide to participate you would sign a form to say you agree, followed by a quick questionnaire.

After this you will undergo any treatment the team looking after you thinks is needed. This will be the same whether you are part of this study or not. This study will not delay any treatment.

At each hospital visit you will be asked to fill in a questionnaire, whilst your limb is exposed to the air (uncovered by clothing) to allow it to adapt to the surroundings. You will be asked to limit your movements for 15 minutes during this time. Then a thermal photograph of your operated and non-operated side will be taken. This will take place at 1 or 2, 4, 6, 12 and 24

weeks following your procedure. If you have suffered a broken bone then taking part in this study will require two extra hospital visits at 4 and 24 weeks after surgery. While this is more than normal, we will be able to closely monitor your healing. If you have a hot, red joint then we would usually monitor this situation fairly closely after hospital discharge and you will require one extra hospital visit at 24 weeks after surgery. If you have a hot, red joint then we will also take thermal images of your limbs each day whilst you are an in hospital before and after your procedure.

If you decline to take part in the study your treatment and care will not be affected.

Treatment

- *Wrist Fractures* - If you have broken your wrist you will probably receive surgery to fix the broken bone with a plate and screws. You may be placed in a temporary cast following the procedure and this will be converted to a removable cast shortly after the surgery. This is routinely performed, and your management will follow normal clinical practice for the hospital. Your cast will be removed to assess the wound and take pictures during hospital visits.

- *Ankle Fractures:* If you have broken your ankle you will probably receive surgery to fix the broken bone. This is usually with a plate and screws and you may be placed in a temporary cast following the procedure and this will be converted to a removable cast shortly after the surgery. This is routinely performed, and your management will follow normal clinical practice for the hospital. Your cast will be removed to assess the wound and take pictures during hospital visits. Your surgeon will advise how much weight you should put through the joint.

- Routine physiotherapy: All groups will see physiotherapists at the hospital and in their follow up appointments as part of normal practice at the discretion of the clinical team caring for you.

- Follow up: After the operation, you will be seen at 1 or 2, 4, 6, 12 and 24 weeks in the hospital clinic. All of this is the standard procedure for patients with your injury or condition, except for the additional clinic appointment at 4 and 24 weeks (as outlined above).

- X-rays and scans: You will have already have had an X-ray or scan to show us whether or not you have a broken bone. All X-rays / scans will be those that are normally performed as part of standard care. The number of X-rays / scans you have, will not be influenced by this study.

Questionnaires and Records

You will be asked to complete a questionnaire at each visit so that we can assess any factors that may be affecting your skin temperatures, fracture healing or risk of infection. The study team can help you complete these whilst you acclimatise (allow your skin to adapt to the outside environment/temperature) for your photograph. This should take around 15 minutes. As infrared cameras cannot see through clothing (or other structures) you will be asked to remove any long sleeves/long trousers covering your affected part of the body and on the other side (opposite limb).

Your thermographic (infrared) photograph will be taken of your affected limb and of the same limb on the other side of your body after 15 minute acclimatisation period. This will allow us to analyse the temperature differences between your limbs so that we can demonstrate what normal temperatures are and see if there are any differences in patients who go on to develop infection.

We will collect data from your hospital about your injury, any blood tests, microbiology (bugs you have grown), histology (how your cells look under microscope) or other treatments you have received. We will collect data on any complications that have occurred, as well as your X-ray/CT and other relevant imaging results. These questionnaires and infrared photographs are a research activity and therefore not something we usually do. With your consent we would also like to store your images in a secure location/computer (as directed by an ethical committee and legal framework) to be later analysed by an automated/machine learning process (advanced data science techniques) to increase our chances of diagnosing infection for future patients.

How will I be contacted?
With your permission we may contact you via: ***Post*** to send you appointment reminders and newsletters; ***Telephone*** to remind you about appointments; ***Email*** with updates. You will have an opportunity to receive a summary of the study once it is complete via either post or email. If you would like this please indicate your preference on the consent form.

Withdrawal from the study
You do not have to take part if you do not want to. If you decide to take part now, you can always change your mind at any point and withdraw from the study. You do not have to give a reason for this. Your rights and your care would not be affected.

If you were to withdraw, we would ask you tell us if you would not want us to contact the hospital for any more information about you. All other information collected up to the time of your withdrawal will be kept.

If you choose not to take part in the study, your available treatment options and your care will not be affected, which you surgeon will discuss with you.

3. What are the possible benefits of taking part?

With your help, this study will inform future research and better our understanding of using thermal cameras to help diagnose infection. You will also benefit from closer supervision of your care and your involvement could help patients in with your condition in the future.

4. What are the possible risks?

There are no new treatments offered during this study, and as such there will be no increased risk beyond your routine care if you were to take part in this study. The clinical team looking after you will discuss the risks of any treatments that they may recommend for you.

5. More information

What happens if there is a problem?
If you have any concerns, you should speak to your surgeon or one of the researchers who can answer your questions (contact details at the end of this document).

If you are harmed due to someone's negligence, you may have grounds for legal action and your rights are not affected by participating in the study.

If you wish to make a complaint, you can do this through the usual NHS procedures by contacting a Patient Advice and Liaison Services (PALS) officer (see contact details at the end of this information sheet).

If you become distressed during the research – we would encourage you to speak to the research team, so that they can try to help you. Again, you are reminded that you are free to withdraw from the study at any time. Even if you do withdraw, you will still have access to the team that are caring for your orthopaedic health in the usual way. For distress specifically related to problems with mental health you will be supported to access usual healthcare pathways such as your general practitioner. The Patient Advice and Liaison Services team can also offer confidential advice and support, and may be able to offer help even if it isn't regarding a specific complaint.

Will my taking part be kept confidential?

We will inform any relevant healthcare professional that may be treating your orthopaedic problem, that you are part of this study, and if necessary, ask for your updated contact details.

Any information that we have about you will be held securely at Hull University Teaching Hospitals or an alternative secure location. You will be given a participant ID number, which will be used to identify you on all study forms and questionnaires. Information will be kept strictly confidential and will be held in line with appropriate legal frameworks. Once anonymised, your data may be shared with Aalborg University Hospital, Denmark who are also taking part in the study.

Only your direct care team or the research team will have access to identifiable information, and anyone who does so will have a duty of confidentiality to you. At the end of the study, the data collected from you will be securely archived, with hard copy data stored for 5 years and electronic data (including thermal images) for 15 years.

What will happen to the results of the study?

After the study has concluded and the data has been evaluated, it will be published in medical journals and presented at conferences. You will not be identified in any reports. You may receive a summary of our findings if you wish. This will be by either email, or postal letter depending on what preference you specify on the consent form.

How will we use information about you?

We will need to use information from your medical records for this research project. This information will include your NHS number, name, contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. In the (unlikely) event of a loss of capacity, the research team would retain personal data collected and continue to use it confidentially in connection with the purposes for which consent is being sought. This could include further research after the current project has ended.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or by asking one of the research team.

How is the study organised?
The study is sponsored by the Research & Development department in Hull University Teaching Hospitals NHS Trust who will manage the study and quality assure study processes.

This research project has been approved by a UK-based Health Research Authority Research Ethics Committee to protect your interests.

Your treating clinician will not receive payments for their involvement in the study. Participation in this study should also not cost you anything.

6. How to contact us

If you need any further information, please contact us:

Lead Investigators:

Professor Hemant Kumar Sharma
Email: h.sharma@hull.ac.uk, *Telephone: 01482674157*

Dr Gavin Barlow
Email: gavin.barlow@york.ac.uk

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Email: arun.watts2@nhs.net

Research Nurse Hull:

Miss Kim Dearnley
Office: 01482 674771, Email: kim.dearnley@nhs.net

Sponsor Data Protection Officer:

Caldicott Guardian Alastair Pickering
Email: alastair.pickering@nhs.net

If you would like independent advice about whether or not to take part, please contact the Patient Advice and Liaison Service (PALS): pals.mailbox@hey.nhs.uk or 01482623065.

You can find independent information on research in general by contacting INVOLVE, the national advisory group of the National Institute for Health Research (telephone: 02380 651088, Email: admin@invo.org.uk, website: www.invo.org.uk).

Thank you for reading this information sheet and for taking the time to consider taking part in this study.