The Leeds Teaching Hospitals NHS
NHS Trust

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Version 3

Trial of Remote Continuous vs Intermittent Vital Signs Monitoring after Major Surgery

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

A large-print version of this sheet is available on request.

You have been invited to take part in a research study. Before you decide if you want to take part, we would like to explain why the research is being done, how we will use the information we have about you, and what the study will involve.

Please read this information carefully, and discuss it with others if you like. Ask us if anything is unclear, or if you would like more information.

Once you have read this information, the study team will talk to you about the study again and you can ask any questions you like.

Part 1 tells you the purpose of the study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Take time to decide whether or not you wish to take part.

Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This study will investigate the use of continuous vital signs monitoring in patients having planned major surgery at St. James's University Hospital, Leeds.

Unfortunately, up to a third of patients who have major surgery will experience a serious complication, such as infection. One of the ways patients are monitored for complications is by charting their vital signs: blood pressure, heart rate, breathing rate and temperature. The nurse looking after the patient will usually check these signs every few hours in the days after surgery. The vital signs are used to form a score, the National Early Warning Score (NEWS), which can alert if the patient becomes unwell.

We are testing a wireless monitoring patch that continuously monitors vital signs: heart rate, breathing rate and temperature. This information is sent wirelessly to a mobile phone carried by the nurse, which alerts if the vital signs become abnormal.

It is thought that continuous monitoring might help detect complications early, but not enough is known about this technology to say for sure. This is why it has to be tested against the current national standard of care: NEWS monitoring.

In order to test this theory, a study will be done comparing the patch system with NEWS monitoring. The main aim is to provide information about whether the research works, and if the patch improves results for patients having major surgery.

Why have I been invited?

Two general surgery wards at St. James's University Hospital are taking part in the study. You will be asked to join the study if you are having planned major surgery and you are likely to return to one of these wards afterwards. You will be given information about the study and allowed time to decide whether you wish to take part.

Do I have to take part?

No. It is up to you to decide whether to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved. If you decide to take part you are free to leave the study at any time and without giving a reason. If you withdraw, unless you object, we will still keep records relating to the treatment given to you, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive. In the unlikely event that, during the study, you are no longer capable of agreeing to take part, any intervention outside of normal care (such as the monitoring patch) will be removed. Information will still be collected

about your hospital stay until you are well enough to give permission again. Your close relatives' views of your wishes may be taken into account.

What will happen to me if I take part?

If you choose to take part, your care in hospital will not differ from standard care.

Patients who enter the study will be randomly allocated to one of two groups. All of the patients will receive standard NEWS monitoring, as usual. Half of the patients who enter the study will also receive the continuous patch monitoring. This decision is made at random, and it is not possible for you or the clinical team to change it.

If you are in the patch group, the patch will be applied in the Recovery Room after your operation. You will be asked to wear the patch on your chest for the whole of your admission, in addition to receiving usual NEWS monitoring.

Two wards at St. James's University Hospital are taking part in the study. If you go to another ward after your surgery, you will not be able to receive a patch. If you go to a high-dependency bed after surgery, but then return to one of the study wards, the patch will be activated when you arrive on the ward. If you move off the study ward during your admission, your patch can be removed.

Everyone who enters the study will be followed during the course of their hospital stay. The information collected will include any complications you experience, including infections, and how quickly they are treated. You will also be followed up if you are moved to a high-dependency ward. Information will be gathered about how long you stay in hospital.

An important part of the study will be to assess how patients and nurses feel about the patch monitoring system. If you receive a patch, you will be invited to fill out a questionnaire and undertake a short interview (15-30 minutes) before you go home.

Once you are discharged from hospital, your participation in the trial will be over.

What are the possible disadvantages and risks of taking part?

If you are in the group that receives standard NEWS monitoring alone, your care will not vary from that of someone who is not taking part in the research, although information about your hospital stay will be collected.

If you are in the group of patients that receives the monitoring patch, you will have the patch applied in the Recovery Room after your operation. This process is painless, but will take 5-10 minutes and may involve some skin preparation of the area on the chest where the patch is applied. This sometimes includes shaving small areas for the patch to stick to. The patch's battery lasts for five days. You will be expected to wear a patch for the whole of your hospital stay. This may mean getting the patch changed a number of times, if you are in hospital for a few weeks.

Once you are wearing the patch, you are free to move about as normal. The patch is

not connected to any machines and so it should not limit your movement.

It is important to remember that your doctors and nurses may not be able to detect complications even if you are wearing the patch, so if you are feeling unwell or have any concerns you should alert a member of staff.

At the end of your hospital stay, the patch will be removed and you will be asked to fill out a questionnaire. You will also be asked to undergo a short interview before going home and/or return to the hospital at a later date to take part in two focus groups, lasting an hour each. If you are not comfortable sharing your views, you may decline these. The interviews and the focus groups will be audio recorded. If you decide to take part in the focus groups, you will be reimbursed for time and travel expenses.

What are the possible benefits of taking part?

If you receive the patch, it is possible that any complication you experience may be detected earlier. However, although you may enjoy wearing the patch, participating in this study may not directly benefit your health. Information gathered from this study may benefit future patients and pave the way for improved care.

What happens when the research study stops?

Your involvement in this study will stop once you are discharged from hospital. After this time your follow up will be as standard treatment.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed due to negligence then you may have grounds for legal action but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you. If you have a complaint about the care you have received you can contact the Patient Advice and Liaison Service (PALS) at: Patient Relations Department, Trust Head Quarters St James's Hospital, Leeds LS9 7TF. Tel 0113 2066261
Email: patientexperience.leedsth@nhs.net

Will my taking part be kept confidential?

If you decide to participate in this study the information collected about you will be handled strictly in accordance with the consent that you have given and the 1998 Data Protection Act. Please refer to Part 2 for further details.

Your contact telephone numbers:

Surgical Trials Unit at St James's Hospital: (0113) 206 4184.

Part 2

What if new information becomes available?

Sometimes during clinical research, new information becomes available regarding the systems being studied. If this happens, we will tell you about it and discuss with you whether you want to or should continue in the study.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue. If the study is stopped for any other reason, you will be told why.

What will happen if I don't want to carry on with the study?

If you withdraw consent from further study treatment, and/or follow-up, your data will remain on file and will be included in the final study analysis.

If you leave the study and do not wish for any further information to be collected, you should inform your clinical care team in order that no further information is collected.

Please note the study team may be required to continue to collect some limited information about you in the case of any unwanted effects you may have as a result of taking part in the trial. This will only be collected if required by the regulatory authorities.

Will my taking part in this study be kept confidential?

If you decide to participate, the information collected about you will be handled in accordance with the consent that you have given and the 1998 Data Protection Act. The information needed for study purposes will be recorded on paper forms and collected by the researchers at St James's University Hospital, Leeds. These forms will be kept for five years and then safely destroyed. Access to the forms will be limited to the researchers involved in the study.

You will be allocated a study number, which will be used along with your initials to identify you on each paper form. Your full name will be included on your consent form and a copy of this will be collected by the researchers and stored securely at St James's University Hospital. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it.

Any audio recordings will be anonymised and destroyed once the relevant information has been obtained. The recordings will be transcribed by a transcription service who will not have access to your name or personal details.

If you would like to be informed of the results of the study, your contact details will be collected and stored securely in a locked office at St. James's University Hospital.

Your data will be entered onto a secure database held on an encrypted laptop belonging to the University of Leeds in accordance with the 1998 Data Protection Act.

Any of your data uploaded to the monitoring system will be linked to your name for clinical purposes. However, Sensium Healthcare (the company who manufacture the patch) will not have access to any personal clinical information about you. Data uploaded to the monitoring system will be downloaded onto a secure computer held at St James's University Hospital at the end of the study and deleted from the monitoring system.

Your healthcare records may be looked at by authorised individuals from the research team, Leeds Teaching Hospitals NHS Trust, the University of Leeds or the regulatory authorities to check that the study is being carried out correctly.

What will happen to the results of the research study?

When the study is complete the results will be used to inform a PhD degree for the lead researcher. The results may be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please ask your doctor. Anonymised results will be shared with the patch company, but they will not receive any names or personal details.

The results of this study will be used to design a much larger study looking at continuous vital signs monitoring, with the potential to help many future patients.

Contact for further information

Please ask any questions you wish before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns, please contact:

Candice Downey or Pauline Walton: (0113) 206 4184 ……
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If you decide to take part, please read and sign the consent form. You will be given a copy of this information sheet. Copies of the consent form will be filed in your notes, with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.