To be on local hospital headed paper

Exploring pulse oXimeter Accuracy across sKin Tones

A study to determine the effect of skin tone on the diagnostic accuracy of pulse oximeters

Nominated Consultee Information Sheet

Version 1.0, 12 April 2022

The EXAKT Study

We would like to invite you to provide your opinion about a patient taking part in a research study

- You are invited to provide your opinion, as an independent nominated consultee, for a patient to be included in a research study.
- You have been approached because there is no personal consultee (relative/friend) available to provide their opinion.
- Please take time to consider this information sheet.
- Ask us if there is anything that is not clear or if you would like more information. Please see 'how to contact us' for contact details.
- Thank you for reading this information. If, in your opinion, you feel the patient would be happy to take part, you will be asked to sign an Opinion Form.

Important things you need to know

- EXAKT is a smaller study running as part of the UK-ROX study, which is looking at oxygen target levels in patients needing extra oxygen as part of their treatment.
- When the patient came into intensive care, they were selected to take part in the EXAKT study.
- We are asking if you think the patient would be happy to take part in the study.
- **The following information is what we would have given to the patient if they were able to consent to taking part.**

Contents

How to contact us

If you have any questions about this study, please talk to your doctor or nurse:

Name of doctor and nurse
Hospital Department
Hospital
Address
Address
Tel:

icnarc intensive care national audit & research centre

1 Why are we doing this study?

What are pulse oximeters?

Pulse oximeters are devices that look a bit like a clothes peg and are placed on the end of a finger. They contain a light which shines through your fingertip, to give an estimate of the amount of oxygen in your blood. Previous research has found that the accuracy of pulse oximeters may be affected by skin tone, but more research is needed.

What are we trying to find out?

We are running this study to understand more about how skin tone affects the accuracy of pulse oximeters. At this hospital, we are testing two different pulse oximeters used by the NHS.

During your stay in intensive care, we placed two additional pulse oximeters on your fingers for 24 hours. The values recorded from these pulse oximeters will be compared to the oxygen values we routinely collect from you whilst in intensive care.

We also measured your skin tone using a specialist device. The device works by shining light at the skin and measuring the light reflected back to the device. This will allow us to make comparisons between the pulse oximeter readings and your skin tone. We hope the information from this study will tell us how accurate pulse oximeters are in people with different skin tones.

2 What are the benefits and risks of taking part?

We cannot promise that you will benefit directly by taking part. The treatment you received whilst in intensive care has not changed as a result of the study and will not change if you decide to take part.

We continued to use the pulse oximeter that we usually use in intensive care, alongside the pulse oximeters we are studying.

We hope that this study will help improve the care of future patients.

3 What will taking part involve?

Do I have to take part?

No. It is up to you whether you want to take part in the study. If you agree to take part, then you will be asked to sign a consent form.

You are free to leave the study at any time without giving a reason. This will not affect your medical care now or in the future and no further information about you will be collected (unless you agree otherwise).

What will happen next?

If you agree to take part, the hospital research team will collect some information from your medical records for use in the study.

4 How will my information be used?

The hospital team have collected information on your skin tone and from the pulse oximeters being studied. They will also collect some information from your medical records. This information will be securely sent from your hospital to the Intensive Care National Audit & Research Centre (ICNARC) who are managing the study and will analyse the results once it is finished.

You can be assured that all sharing and storing of information about you will be done securely and will only be available to people who are fully authorised to use it. The databases are used to support many research studies and there are strict controls in place to ensure confidentiality. We will follow the law (Data Protection Act 2018) by making sure your information is kept private and secure.

We will need to use information that is already routinely recorded in your medical records for this study. This will include information usually held by the NHS (including by [Local NHS Trust] and ICNARC). To obtain this data we will collect a small amount of other identifiable information about you (date of birth and NHS number).

ICNARC will keep the identifiable information about you from this study for no longer than one year after the study has finished (unless you have agreed otherwise). The rest of the research data will be kept for a minimum of ten years. [Local NHS Trust] will keep identifiable information about you from this study for five years after it has finished.

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 stop being part of the study at any time without giving a reason, but we will keep the information on events that already happened up to when you made your decision.

Future research

Information collected from research studies can be used to answer many important research questions, beyond those planned in the original study. This has the potential to provide real benefit to patients, the NHS, and the scientific community.

We would like your permission to share anonymous information about you with other researchers if we feel it could contribute to answering important questions. Because it's anonymous, the researchers would not be able to identify you from this data.

Where can I find out more about how my information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to: UK-ROX@icnarc.org
- at <Insert link to EXAKT privacy policy here>

5 More information about the study

What will happen to the results of the study?

The results of the study will appear in scientific journals. You will be able to find the results on the Intensive Care National Audit & Research Centre (ICNARC) website (www.icnarc.org) within a year after the study is completed. It will not be possible to identify any person who has taken part in the study in any journals, reports, or articles.

Who is funding and organising the study?

The study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme. Professor Daniel Martin is the senior intensive care consultant who is leading the study. ICNARC are managing the study.

The research team are qualified to do this study as they have all the specialties and skills needed, including caring for patients, and doing health research. Patients who have been in intensive care have been involved in developing the study, including this leaflet and how you were asked to take part.

Who has reviewed the study?

All NHS research is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the South Central – Oxford C Research Ethics Committee.

What if there is a problem?

Complaints: If you have a concern about any aspect of the EXAKT study, you

should ask to speak with the Principal Investigator <Insert NAME> or research team at your hospital who will do their best to answer your questions.

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 or the Patient Advisory Liaison Service (PALS), contactable on <Insert PALS number>. You may also have the right to lodge a complaint with the Information Commissioner's Office (ICO) (www.ico.org.uk).

Harm: In the unlikely event that something has gone wrong and you were harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against [insert NHS Trust NAME] but you may have to pay your legal costs. If you are harmed due to the design or management of the study, you may have grounds for legal action for compensation against the Intensive Care National Audit & Research Centre (ICNARC). The normal NHS complaints procedures are still available to you (if appropriate).

To leave the study at any point, you can contact the Principal Investigator (the person leading the study at this hospital) using the details outlined in Section 6 of this information sheet, or by contacting the Intensive Care National Audit & Research Centre (ICNARC) by phone on 020 7269 9277 or email to UK-ROX@icnarc.org.

6 Contacts for further information

For more information about the EXAKT study, contact the Principal Investigator or Research Nurse at your hospital:

Principal Investigator
[Insert name, position]
[Contact number]

Research Nurse
[Insert name, position]
[Contact number]

and visit the EXAKT website:

<Insert link to EXAKT website here>

If you are unhappy with any aspect of the study and do not wish to speak to the research staff listed above, please contact the Patient Advisory and Liaison Service (PALS):
[Insert PALS contact details here].

We are very grateful that you are considering taking part in this study and thank you for your time.