To be on local hospital headed paper

Intensive Care Unit Randomised Trial Comparing Two Approaches to OXygen Therapy

Patient Information Sheet

Version ~~1.2, 19 March 2021~~1.0, 12 April 2022

The UK-ROX Study

We would like to invite you to take part in a research study

- Please take time to consider this information sheet. You may wish to talk to your friends and family about this study before you decide if you would like to continue to take part.
- You are free to decide whether your information is included in the research. If you do not take part, this will not affect the care you receive.
- You can stop taking part in the study at any time, without you giving a reason.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you agree to take part, you will be given a copy of this information sheet and asked to sign a Consent Form. You will get a copy of that as well.

Important things you need to know

- When you came into intensive care, you needed extra oxygen as part of your treatment.
- We are studying whether using a lower oxygen target to guide oxygen treatment might lead to better outcomes for patients when compared with the approach currently used in the NHS.
- As this was an emergency, you may have already been treated using the lower oxygen target or continued to receive the usual care.
- This type of research is called 'research without prior consent' and is done in emergencies when comparing treatments to find out which is best.
- We are now asking if you would like to continue to take part in the study.

Contents

1 **Why are we doing this study?** Page 2

2 **How was my oxygen treatment decided?** Page 2

3 **Why am I being asked after I have been given the treatment, rather than before?** Page 2

4 **What are the benefits and risks of taking part?** Page 2

5 **What will taking part involve?** Page 3

~~5~~6 **The EXAKT sub-study** Page 4

~~6~~7 **How will my information be used?** Page 4

~~7~~8 **More information about the study** Page 5

~~8~~9 **Contacts for further information** Page 5

Formatted: Font: 11 pt, Bold, Font color: Auto

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:

1 Why are we doing this study?

Many people who come into intensive care need extra oxygen to help support their breathing. Oxygen is one of the most common treatments given to patients in intensive care.

How is oxygen treatment usually decided?

Nurses and doctors adjust the amount of oxygen given to patients based on how much oxygen is in their blood. Currently there is not much evidence about the best amount of extra oxygen that nurses and doctors should give during treatment. This means that different blood oxygen targets are used in different hospitals, but usually these targets will be around 96-97% of oxygen in the blood.

What are we trying to find out?

Some recent evidence suggests that giving slightly less extra oxygen during treatment may be beneficial, but more research is needed.

We want to find out whether using a slightly lower blood oxygen target of around 90%, to guide treatment might lead to better outcomes for patients when compared with the approach currently used in the NHS.

This is a large national study. We hope to include 16,500 patients from around 100 NHS intensive care units across the country. We hope that this research will help to improve the future treatment of patients in intensive care in the UK and around the world.

2 How was my oxygen treatment decided?

To make sure it is fair, a computer programme is used to randomly put patients into one of two groups:

- Group 1 receive extra oxygen using the lower target of around 90%
- Group 2 receive extra oxygen just as they would have outside of the study (usual care)

We will find out which treatment is most beneficial by using information that is already routinely collected in your medical records. We will also send a short health questionnaire to some patients. We will monitor the study closely and, if one treatment is better or worse, we will stop the study.

3 Why am I being asked after I have been given the treatment, rather than before?

As you were very ill and on a breathing machine (ventilator) when you needed the extra oxygen, it may not have been appropriate to ask for written consent from you at the time. We have approached you about the study as soon as possible.

This type of research is called ‘research without prior consent’, a method of consent which is commonly used in emergency studies.

4 What are the benefits and risks of taking part?

We cannot promise that you will benefit directly by taking part.

We know that extremely high and extremely low oxygen levels can cause damage to our bodies. The purpose of this study is to look at the effect of a small

reduction in how much extra oxygen we give.

The benefits and risks of giving slightly less extra oxygen are unclear at this time, which is why this research is needed.

You have been, and will continue to be, monitored closely by your doctors and nurses. If they feel it is in your best interest to change the amount of extra oxygen you are given, then they will do so.

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

5 What will taking part involve?

Do I have to continue to take part?

No. It is up to you if you want to continue 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 would 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 continue to collect some information from your medical records for use in the study.

Will my information be sent anywhere else for the study?

The hospital research team will continue to collect some information from your medical records for use in the study. This information will be securely sent to the Intensive Care National Audit & Research Centre (ICNARC) who are managing the study and will analyse the results once it is finished.

Other personal information about you (such as your name, date of birth, postcode and NHS number) will be shared between the hospital, ICNARC and the NHS national databases (held by NHS Digital and NHS Wales Informatics Service) so that your well-being (survival and hospital admissions) can be monitored as part of the study.

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.

Is any follow-up required for the study?

After three months, we will send a short health questionnaire to a small group of patients taking part in the study, to find out how they are doing.

The questionnaire takes around 15 minutes to complete and a stamped addressed envelope will be provided so that there will be no cost to you.

We will collect your contact details if you are happy to be sent the questionnaire. We may telephone you after a few weeks to check you received it.

Contributing to a global study

The information collected from patients in this study will also be included in a global study of extra oxygen use in around 40,000 patients from intensive care units around the world.

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 anonymised information about you with other researchers if we feel it could contribute to answering important questions. Examples of this would be your age, treatments you received or how long you stayed in hospital. It would not be possible to identify you from this data.

6 The EXAKT sub-study

As part of UK-ROX we are also running a smaller study called the EXAKT sub-study. The aim of EXAKT is to understand more about how skin tone affects the accuracy of 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 the blood. Previous research has found that the accuracy of pulse oximeters may be affected by skin tone, but more research is needed.

We are testing two pulse oximeters used by the NHS. The values recorded from these pulse oximeters will be compared to the oxygen values routinely collected from you whilst in intensive care. The pulse oximeters we are studying were placed on your fingers for 24 hours. During this time, we continued to use the pulse oximeter that we usually use 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 this information will tell us how accurate these pulse oximeters are in people with different skin tones.

7~~6~~ How will my information be used?

We will follow the law (Data Protection Act 2018) by making sure your information is kept private and secure. As described above, we will need to use information that is already routinely recorded in your medical records for this study. This will include information already usually held by the NHS (including by [Local NHS Trust], NHS Digital and NHS Wales Informatics Service) and the Intensive Care National Audit & Research Centre (ICNARC).

For a small group of patients in the study, we will also record information about their oxygen treatment so that we can check that the study is going as planned. Only authorised 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.

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) and 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 information about you that we already have. If you decline participation, the study will keep information on treatments and procedures that happened up to when you made your decision (unless you don't wish us to) but no information about treatments and procedures after your decision will be included. Similarly, if you later choose to stop taking part in the study, we will keep the information on events that already happened up to your decision.

Formatted: Space After: 0 pt

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 https://www.icnarc.org/Our-Research/Studies/Uk-

Rox/Information-For-Patients/Privacy-Policy

- at <Insert link to EXAKT privacy policy here>

87 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 ICNARC's 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 UK-ROX study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme. The EXAKT sub-study is also funded by the NIHR. Professor Daniel Martin is the senior intensive care consultant who is leading the study along with Mr Paul Mouncey who is an experienced researcher. The Intensive Care National Audit & Research Centre (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. UK-ROX and EXAKT ~~This study~~ ha~~s~~ves 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 UK-ROX or EXAKT, 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 9~~8~~ 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.

9~~8~~ Contacts for further information

For more information about UK-ROX or EXAKT, 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~~Visit the UK-ROX website:

https://www.icnarc.org/Our-Research/Studies/Uk-Rox

Visit the EXAKT website:

<Insert link to EXAKT site 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.

Formatted: Highlight

Formatted: Highlight