Thank you for taking the time to read this leaflet

If you have any questions about UK-ROX you can speak to a member of the UK-ROX team in this unit:

<INSERT PI NAME>

<INSERT UK-ROX TEAM MEMBER NAME>

Please see the main Participant Information Sheet for full details of the study.

icnarc intensive care national audit & research centre

NIHR | National Institute for Health Research

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

Research Ethics Committee Reference Number: 20/SC/0423

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Information Leaflet

v1.~~0, 20 October 2020~~ 1, 19 March 2021

UK-ROX 90

Intensive Care Unit Randomised Trial Comparing Two Approaches to OXygen Therapy

<INSERT HOSPITAL/TURST LOGO HERE>

What is the purpose of the study?

Oxygen is one of the most common treatments given to patients in the intensive care unit. Doctors and nurses adjust the amount of extra oxygen given to patients based on how much oxygen there is in their blood.

Currently, there is not much evidence about the best amount of extra oxygen to give to patients ~~in the blood to use~~ 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. ~~As a result, doctors and nurses tend to use oxygen at the higher end of the recommended range. We know that extremely high and extremely low oxygen levels can cause damage to our bodies.~~ Recent research suggests that giving slightly less extra oxygen may be beneficial, but more research is needed.

We are therefore studying the effect of a small reduction in how much extra oxygen we give. The full benefits and risks of giving slightly less extra oxygen are unclear at this time, which is why this research is needed. Our aim is to find out whether using slightly lower amounts of extra oxygen lead to better outcomes. ~~in patients who need extra oxygen.~~

What will happen if I take part?

When people are put on a breathing machine (ventilator) and given extra oxygen, it is usually an emergency situation where decisions need to be made very quickly. The clinical team will therefore enrol patients into the research and focus on delivering the treatment.

Half of patients will be treated using the slightly lower oxygen target of around 90% ~~(90-93% of oxygen in the blood)~~. The other half will receive the usual amount of extra oxygen that they would have received if they were not involved in the trial.

Patients and/or their relatives will be informed about the research and approached for their consent/agreement when the emergency situation is over. This method of consent is commonly used in studies in the intensive care unit.

All patients involved in the trial will be monitored closely and will receive all standard NHS care as and when they need it.

NHS
National Institute for Health Research

What information will be collected?

Some information about participants' hospital stay will be collected from hospital medical records. Other important health information will be collected from national NHS databases. Some participants will also be sent a short health questionnaire after three months. This will allow us to compare the two groups in the study to find out which treatment is most beneficial. All information collected is kept secure and confidential.

Do I have to take part?

It is up to participants if they want to take part or not. This decision will not affect any of the future care participants receive.

What next?

Patients and/or their relatives may be approached by a member of our team, who will be able to go through the research in more detail. A full information sheet will also be provided.