

# **Mega-ROX: The Mega Randomized Registry Trial Comparing Conservative vs. Liberal OXygenation Targets**

## **INFORMATION SHEET**

### **PURPOSE OF THIS STUDY**

The purpose of the Mega-ROX study is to compare two approaches to oxygen therapy to determine which is more effective in improving survival in intensive care unit (ICU) patients who need ventilation (a breathing machine).

This study is led by Prof Madiha Hashmi at the Dr Ziauddin Group of Hospitals and has been approved by the Ziauddin University Ethics Review Committee (ERC).

### **BACKGROUND**

Oxygen is essential for life and is given to all patients on a ventilator (a breathing machine). Often these patients receive more oxygen than they need. Some research suggests that giving more oxygen than is needed may be harmful while other research suggests it may be beneficial.

This study focuses on the oxygen therapy patients receive in the ICU to find out which approach to oxygen therapy is better.

### **WHAT DOES PARTICIPATION IN THE STUDY INVOLVE?**

Patients included in the Mega-ROX study will receive one of two approaches to oxygen therapy. One approach involves using a higher level of oxygen, while the other uses a lower level. The approach to oxygen therapy will be randomly selected for all patients included in this study. This means the oxygen therapy will not be decided by the treating clinician. The ICU treating team has determined that both approaches to oxygen therapy are appropriate for your relative and agrees with their participation in this study.

All information that we require for this study is routinely collected as part of the care we provide in the ICU, and no in-person follow-up is required. All participants will be reviewed daily during their ICU stay and contacted only once after 3 months after discharge via phone call.

### **WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?**

Patients who are included in the Mega-ROX study are expected to have a higher chance of survival than patients who are not in the study. This is because the study uses a method to learn from previous patients to improve chances of new patients receiving the best treatment.

Both approaches being tested have no additional risks beyond those associated with standard ICU protocols. If your relative participates in this study, their information can be used to help future patients receive the best treatment.

### **WHO PAYS FOR THE STUDY?**

There are no costs associated with participating in this study for you or your relative. Participants and treating clinicians will not be paid. However, the research team will receive a payment from the international funders of this study for each patient involved in the study to cover the costs of conducting this study.

### **WHAT IS THE COMPENSATION POLICY FOR COMPLICATIONS?**

The treatment approaches in this trial are considered safe. Clinical trial insurance is in place for any serious, unexpected adverse events that occur specifically as a result of participation in this study.

## **WHAT ARE MY RELATIVE'S RIGHTS?**

### Voluntary Participation & Withdrawal

Participation in this study is entirely voluntary. Because your relative cannot decide whether to participate in this study at the moment, your views about whether they would want to participate are important. Refusal to participate will not affect the patient's clinical care. The treating clinician and study team will let you know when it is appropriate to tell your relative about their participation in this study and will support you to inform them, if needed.

If you change your mind about your relative's participation, please let us know. You do not have to give a reason. You or your relative can withdraw from the study at any time and they will continue to receive the best possible care.

### Privacy & Confidentiality:

You and your relative have the right to privacy, and all information collected during this study is confidential as per the applicable laws and regulations. In the study database, participants will only be identified by a unique number. No data that could be used to identify participants will be taken from the medical notes. The data collected for the study may be viewed by relevant research, ethics and regulatory authorities to check that the study is being carried out correctly. All staff have a duty of confidentiality to research participants.

## **WHAT HAPPENS AFTER THE STUDY?**

Study data will be stored in a secure location for a period of 15 years after the study is complete. This study is likely to be completed in 2025 and the results will be published in an academic journal and on our website <https://zu.edu.pk/ccrg/>. If you agree, we will send the results of this study to you directly over the phone or via email.

If you have any questions, concerns or complaints about the study at any stage, you can contact the study investigator ([madiha.hashmi@zu.edu.pk](mailto:madiha.hashmi@zu.edu.pk)) or ethics committee ([zu.erc@zu.edu.pk](mailto:zu.erc@zu.edu.pk)) with the reference code 2680920AKPUL. For more information about this trial, please visit <https://zu.edu.pk/ccrg/>.