The Mega Randomized Registry Trial Comparing Conservative vs. Liberal OXygenation Targets (Mega-ROX)

INFORMATION SHEET

INTRODUCTION:

Oxygen is essential for life and is given to all patients on life support (a breathing machine). Often these patients receive more oxygen than they need. Some research suggests that giving more oxygen than is needed to achieve desired oxygen levels in the body may be harmful while other research suggests that it is not, and it may even be beneficial.

This study compares two ways of giving oxygen to patients on life support (a breathing machine). The first is to give a little more oxygen and the second is to give a little less. Both approaches are safe but is not clear which approach is the most effective.

All patients in this study can be allocated to either of the approaches to oxygen therapy being tested. However, the study is designed so that as the chances that one approach is better for patients with particular problems increases, the number of new patients given oxygen using that approach also increases. In a sense this means that every patient in this study benefits from the information gained from previous patients. If you choose to participate in this study your information can now be used to help future patients receive the best treatment.

PURPOSE OF THIS STUDY:

The purpose of the Mega-ROX study is to determine the effect of two approaches to oxygen therapy on the risk of death in patients who need emergency life support (a breathing machine) in the ICU.

WHAT DOES PARTICIPATION IN THE STUDY INVOLVES?

Patients are enrolled in the Mega-ROX study if they require emergency life support (a breathing machine) in the ICU. This study affects the oxygen therapy patients receive in the ICU. It does not affect any other aspect of treatment.

All information that we require for this study is routinely collected as part of the care we provide in the ICU and there is no follow-up required.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Because information from previous patients is used to increase the chances that future study patients receive the best treatment, patients who are included in the Mega-ROX study are expected to have an overall lower risk of death than patients who are not in the study. The ICU treating team only includes

patients when they consider that the approaches to oxygen therapy used in this study are appropriate. Both approaches being tested have no specific known risks.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Patients who decide not to participate in this study will continue to receive the oxygen therapy they were assigned in the study because this treatment is the one that is most likely to benefit them.

Study data will be stored in a secure location for a period of 15 years after the study is complete.

WHO PAYS FOR THE STUDY?

There are no costs associated with participating in this research project, nor will participants be

paid.

WHAT IF SOMETHING GOES WRONG?

The treatment approaches in this trial are both broadly safe. Clinical trial insurance will be in place, for serious adverse events specific to taking part in this study.

WHAT ARE MY RELATIVE'S RIGHTS?

Overall, patients in this study are expected to have a lower risk of dying than similar patients who are not in this study. Your relative was enrolled in this study, because they were too sick to provide informed consent and the treating team considered that being in this study was in their best interests and because oxygen needs to be provided immediately to patients requiring life support (a breathing machine).

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. If you do not want your relative to participate in this study, please tell us. You do not have to give a reason.

Your relative has the right to privacy and all information that is collected during this study is confidential to the extent permitted by the applicable laws and regulations. In the study database participants will be assigned a unique number and will be identified only by this number. No data which could be used to identify participants will be transferred from the medical notes.

As soon as your relative recovers, they will be given the opportunity to decide whether they would like to continue to participate in this study for themselves. If they choose not to participate, they can do so without giving a reason and will continue to receive the best possible care.

The identity of participants will be kept confidential at all times. The data collected for the study may be viewed by study monitors, members of the Research and Ethics Committee, or other relevant regulatory authorities or their approved representatives to check that the study is being carried out correctly. All staff have a duty of confidentiality to research participants and nothing that could reveal their identities will be disclosed by these persons.

If you have any questions, concerns or complaints about the study at any stage, you can contact the study investigator Dr Madiha Hashmi and the trial coordinator Dr Ayesha Siddiqui on 0213-5862937 (ext.4461).