

**This document is a translation of the Danish “Skriftlig deltagerinformation, HOT-ICU, patienten” version 1.3, August 21<sup>st</sup> 2018. It has been prepared according to Danish regulations. As you may require additional or different information according to your national regulations please feel free to change the document.**

## **FOR THE PATIENT**

**We would like to ask if you want to participate in a medical research project dealing with critically ill patients admitted to an intensive care unit.**

You have been seriously ill and were in need of immediate treatment in the intensive care unit. You have participated in a medical research project. Because of your condition, we were not able to inform you and ask you directly if you wanted to participate in the trial.

Now that you are improving, we will ask you if you want to continue participating in the trial. You must fully understand what the trial is about, and why we are conducting it. We kindly ask you to read the information below carefully.

You will be offered a conversation with a person from the research group, where you will be given a more in depth understanding of the trial and you can ask questions. You are welcome to bring a family member, a friend or an acquaintance to this conversation.

If you decide to continue your participation in the trial, we will ask you to sign the attached consent form. Remember that you have the opportunity to consider your decision before signing.

It is voluntary to participate in the trial. You may at any time without further explanation withdraw your consent. Participation in the trial will not have any influence on your overall treatment.

### **Background**

Critically ill patients acutely admitted to an intensive care unit with respiratory failure have a life threatening condition due to the reduced ability of the lungs to absorb oxygen. Therefore, the patients are treated with supplemental oxygen to ensure adequate oxygen supply to the tissues. Oxygen, which is a medical drug, is given through the airways and absorbed via the lungs into the blood. Oxygen however, is also harmful, especially for the affected lung tissue when it is given in concentrations that exceeds the atmospheric oxygen content (21%). The fear of not getting enough oxygen to the body's cells in acute lung failure causes oxygen to be administered very liberally and therefore patients admitted to intensive care units often have high levels of oxygen in the blood.

The optimal range of oxygenation in the blood in critically ill patients in an intensive care unit is unknown. Very low concentrations of oxygen in the blood lead to higher mortality, but more and more studies show a tendency towards several serious side effects and perhaps an increased mortality when a high level of

oxygen in the blood is targeted. Studies have shown that it is safe to aim for lower values of oxygenation in critically ill patients than the values used up until now.

It is unresolved whether lower oxygenation in the blood overall is beneficial or harmful to critically ill patients in intensive care units and there is thus a great need of a trial that clarifies this.

### **Purpose of the trial**

The purpose of the trial is to assess whether a lower level of oxygenation in the blood has beneficial effects in critically ill patients admitted to an intensive care unit with respiratory failure.

### **Course**

You were admitted to the intensive care unit and treatment was immediately initiated because your condition required it. In relation to the research project you were randomly treated with oxygen equivalent to a lower level of oxygenation in the blood or similar to the usual standard, from the time you were admitted to the intensive care unit.

Before trial inclusion an independent physician not involved in the trial approved your participation. As soon as possible after trial inclusion your relatives and yet another physician not involved in the trial were contacted and informed. Both your relatives and this physician had to provide written consent for the trial to continue. Aside of the trial medication (oxygen) you have also received the usual treatment for your medical condition.

The trial duration is from admission to the intensive care unit until discharge from the intensive care unit and will continue if you are re-admitted in a participating intensive care unit up until a maximum of 90 days after you entered the trial. After one year, we will contact you again to ask about your quality of life. In addition to the physician in charge of the trial (as stated in this information letter), doctors and nurses working in the intensive care unit contributed by practical implementation of the trial.

### **Discontinuation of the trial**

As a participant, you can at any time without justification withdraw from the trial. Withdrawal will not affect your relations to the physicians in the intensive care unit or your treatment. You will continue to receive the treatment that is standard for your medical condition.

### **Advantages of the experiment**

Participation in the trial is beneficial for you because the oxygen treatment will be followed closely in both group. Also, by participating you can help to ensure that we acquire information on whether it is beneficial for critically ill patients to receive lower levels of oxygen supplementation. Thus, the collected data will result in an improved treatment of patients in the intensive care unit.

### **Disadvantages of the experiment**

There is no disadvantages in your trial participation.

### **Side effects, risks and complications**

Oxygen is the most commonly used drug in an intensive care unit. Very few adverse reactions of oxygen have been recorded. These include pneumonia, collapse of lung tissue and acute lung failure. The two first mentioned are often transient and mild, while the last mentioned is a rare but serious adverse reaction. All patients admitted acutely to the intensive care unit with respiratory failure have these changes as a result of the underlying disease which led to the respiratory failure and it is therefore not possible to distinguish these from adverse effects directly triggered by oxygen therapy.

All patients admitted to intensive care unit will continuously be monitored with measurement of their oxygen saturation in the blood and be treated by well-trained staff with extensive experience in treatment of critically ill patients. In both groups of patients the aim is to keep the oxygen level in the blood above critical low values. Therefore, no risks are related to trial inclusion.

### **Patient Compensation**

Damage caused by the study drugs is very unlikely in this study. However, if an injury occurs as a result of the study drugs you are covered by the public patient insurance. If you want to complain about anything related to your participation in this trial, you can obtain instructions from the research group or from the patient counsellor in your country or region.

### **Privacy and confidentiality**

All information will be treated confidentially. When reporting results and when publishing the results of the trial you will remain anonymous. The research group and the Good Clinical Practice monitoring group have access to your entire medical record to ensure that the trial is carried out as described within the protocol. From your medical records we will use information about past medical history, surgical procedures during this hospitalisation, blood test results, medication, treatment and events in the intensive care unit. Anyone with access to the journal is subject to confidentiality.

### **Economy**

The idea for the trial comes from Professor Bodil Steen Rasmussen, Aalborg University Hospital. Together with PhD student Olav Lilleholt Schjørring, Aalborg University Hospital, Bodil Steen Rasmussen is responsible for planning and conduct of the trial. The responsible investigators are employed at Aalborg University Hospital and have no financial interests in the study. The study is funded by the Innovation Fund Denmark (5,642,428 DKK), the Obel Family Foundation (800,000 DKK), Regionernes Medicinpulje (575,000 DKK), the Danish Society of Anesthesiology and Intensive Medicine (DASAIM) (43,000 DKK), and the ICU Symposium Hindsgavl (30,000 DKK). All funding is unrelated to the pharmaceutical industry. Principal Investigator Bodil Steen Rasmussen is a member of DASAIM, but is unrelated to the contributors. The money represents a research fund administered by Professor Bodil Steen Rasmussen, which is subject to external audit.

### **Access to study results**

When the trial is completed, we will determine survival and occurrence of adverse events among participants. The results will be published in an international scientific journal as well as on the website of Aalborg University Hospital and on the trial website [www.cric.nu/hot-icu](http://www.cric.nu/hot-icu). If you want to know the results of the project and any consequences for you, you can tick this off on the consent statement.

**Inquiry of participation in a medical research project for patients admitted to an intensive care unit**  
Handling Oxygenation Targets in the Intensive Care Unit (HOT-ICU)  
04-Oct-2018, version 1.3

**Contact**

We hope that you with this information feel sufficiently informed and able to make a decision on your potential participation. For further information please feel free to contact one of the investigators below.

Sincerely

**Local Principal Investigator**

**Name**

Title

Department

Institution

Working address

Phone

E-mail

**Sponsor and Principal Investigator**

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