UNIVERSITY MEDICAL CENTER SCHLESWIG-HOLSTEIN
CAMPUS KIEL
DEPARTMENT OF ANESTHESIOLOGY AND INTENSIVE CARE MEDICINE
DIRECTOR: PROF. DR. MED. STEINFATH

Information for Patients
Participation in the Clinical Study:

Automatic Adjustment of Oxygen Concentration by the Ventilator

Dear Patient,

We would like to ask if you are willing to participate in the clinical study described below. Clinical studies are essential for gaining insights into the effectiveness of new therapies. Participation in such a study is entirely voluntary. You will only be included if you provide your written consent.

What is the purpose of the planned study?

As part of your treatment at UKSH, mechanical ventilation in the intensive care unit is required. During this process, a ventilator pumps a mixture of oxygen and air into your lungs. Typically, the oxygen concentration on the ventilator is manually adjusted. However, the ventilators used at UKSH have a feature that allows the oxygen concentration to be automatically adjusted based on your oxygen saturation, measured with a finger clip (pulse oximetry).

This automatic adjustment aims to better match the oxygen concentration to your actual oxygen needs. The goal of the planned study is to investigate whether this automatic adjustment leads to fewer and shorter deviations of oxygen saturation levels outside the medically prescribed target range compared to manual adjustments.

How does the study work?

If you agree to participate in the study, a random process will decide whether the oxygen concentration is adjusted manually or automatically by the ventilator's oxygen control system. This process is called "randomization" and is similar to flipping a coin.

During the study, data from the ventilator and other routine data collected as part of your intensive care treatment will be recorded for scientific analysis. Apart from the automatic adjustment of the oxygen concentration, no additional measures will be taken.

When does the study end for me?

The study will end when mechanical ventilation is no longer required, or after 28 days at the latest. However, you have the right to withdraw your consent and stop participating in the study at any time. If you choose to withdraw, the study will end immediately for you.

What potential benefit do I have from participating in the study?

You are unlikely to experience any personal benefit from participating in this study. However, by taking part, you may help contribute to scientific knowledge that could benefit the treatment of patients requiring mechanical ventilation in the future.

What are the risks of the planned study?

Based on current scientific knowledge, we do not expect any additional risks from your participation in this study. This is primarily because, in addition to monitoring your blood oxygen levels via the ventilator, a separate monitoring device will continuously track your oxygen concentration. This ensures that the medical staff can respond to any changes at any time. If necessary, the automatic oxygen adjustment by the ventilator can be stopped or overridden by the medical or nursing staff at any time.

Will I incur any costs or receive compensation for participating in the clinical study?

You will not incur any costs for participating in this clinical study, and you will not receive any financial compensation for your participation.

What happens to my personal data?

The collected study findings and data will be recorded and then processed in a pseudonymized form. Pseudonymized means that no names or initials will be used; instead, a number or letter code along with your age in years will be assigned.

The processing of personal data of the patient you represent will be carried out for the purposes of scientific research by UKSH staff, who are bound by medical confidentiality.
If you have any questions regarding data protection, you can contact the study leadership (contact details below) as well as the data protection officer of UKSH, Dr. Stefan Reuschke (email: datenschutzbeauftrager@uksh.de; phone: +49 431 50014181). You have the right to request information about the data we store that pertains to you and, if necessary, request its deletion. Please contact the study leadership for this purpose.

Contact Information of the Study Team

Principal Investigator and Responsible Person for Data Processing:
Priv.-Doz. Dr. med. Dirk Schädler
Klinik für Anästhesiologie und Operative Intensivmedizin
Universitätsklinikum Schleswig-Holstein, Campus Kiel
Arnold-Heller-Str. 3, Haus R3
D-24105 Kiel
Tel.: 0431/50020800
Fax: 0431/50020804
Email: dirk.schaedler@uksh.de

Additionally, in the case of unlawful data processing, you have the right to file a complaint with a supervisory authority. The competent supervisory authority for Schleswig-Holstein is:

Unabhängiges Landeszentrum für Datenschutz Schleswig-Holstein
Holstenstraße 98
24103 Kiel
Telefon: 0431/988-1200
Telefax: 0431/988-1223
E-Mail: mail@datenschutzzentrum.de
https://www.datenschutzzentrum.de

The pseudonymized data may also be shared with scientific collaborators of UKSH for scientific analysis. The results of the study will be published in a scientific journal. This will be done in full compliance with legal data protection regulations.

Was the study reviewed by an ethics committee?

The conduct of the study has been reviewed by an independent ethics committee regarding ethical and legal concerns. The ethics committee raised no objections to the study being conducted.

Can the decision to participate in the study be reversed?

Participation in the study is completely voluntary. **You can withdraw your participation at any time without facing any disadvantages.** If you have any questions, please contact the following doctors from the Department of Anesthesiology and Surgical Intensive Care Medicine:

Priv.-Doz. Dr. Dirk Schädler
Priv.-Doz. Dr. Tobias Becher
Dr. Matthias Lindner
Dr. Florian Roßkopf
Dr. Armin Sablewski
Dr. Christine Eimer
Dr. Phil Klose
Dr. Helene Selpien
Nina Schulz-Ruthenberg
Corinna Buchholz

If you decide to allow the patient you represent to participate in the study, we kindly ask for your signature on the consent form. A copy of the patient information and consent form provided to you is for your records.

We sincerely thank you for your cooperation.

„Automatic Adjustment of Oxygen Concentration by the Ventilator“

Consent Form for Patients

Dr. [Name of Doctor] has provided me, [Patient's Name], with a detailed explanation about the nature, significance, and scope of this clinical study, as well as the procedures and implementation involved.

I have read and understood the written information for patients. I was given sufficient time and opportunity to ask questions. My questions have been answered thoroughly and to my satisfaction. I have been informed that if I have any further questions during the course of the study, I can contact the principal investigator, who will provide answers to the best of their knowledge and ability.

I consent to the collection of my medical and study data within the framework of this clinical study, both in paper form and on electronic storage devices, in pseudonymized form (without using my name). I understand that these data will be stored for 20 years and may be used for scientific publications. If necessary, the collected data may be shared in pseudonymized (encrypted) form with scientific collaborators of UKSH. I am aware that I can withdraw this consent at any time without giving a reason, and that no disadvantages will result from this. Upon withdrawal, all collected data will be deleted upon my request, unless complete anonymization has already been performed.

I, [First Name, Last Name], born on [Date of Birth], agree to participate in the above-mentioned study.

I have received the patient information and a copy of the consent form.

Date and Signature of Patient: _____

Date and Signature of Doctor: _____