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RQCal Study

Will the Use of Respiratory Quotient “RQ” to Optimize Nutrition Therapy With Indirect Calorimetry Improve Treatment Outcomes for Intensive Care Unit (ICU) Patients?

Organization's Unique Protocol ID : **RQ 447/24**

Protocol

Title of the study: Will the use of respiratory quotient “RQ” to optimize nutrition therapy with indirect calorimetry improve treatment outcomes for intensive care unit (ICU) patients?

Introduction and assumptions of the research project:

Patients treated in intensive care units (ICUs) require comprehensive treatment. Nutrition is an important and integral part of this therapy. Both insufficient and excessive calorie intake are associated with poorer prognosis and increased mortality in ICU patients. Furthermore, the caloric requirements of patients in life-threatening conditions in the ICU are characterized by periods of hypo- and hypermetabolism, which, if nutrition is not optimized, expose patients to overfeeding or underfeeding. Therefore, monitoring resting energy expenditure (REE) using indirect calorimetry has become the “gold standard” in the ICU. Previous methods based on mathematical formulas for calculating REE were characterized by insufficient correlation with actual demand. Indirect calorimetry uses measured exhaled carbon dioxide and the concentration of oxygen administered. Then, taking into account patient-dependent parameters such as gender, height, and weight, it indirectly calculates energy expenditure, which corresponds to caloric demand. By dividing the volume of CO₂ released by the volume of O₂ absorbed, investigators can obtain the respiratory quotient (RQ). This quotient is related to the type of diet and is, for example, 0.7 for fats, 0.8 for proteins, and 1.0 for carbohydrates. Its value also changes with nutritional status. High values may suggest an excessive energy supply (relative to demand), while low values may indicate a calorie deficit. Some authors suggest that the RQ ratio could potentially be used to further optimize nutritional status. Currently, however, due to insufficient research, it is mainly used in clinical practice to assess

the accuracy of recording and monitoring calorimetry. This study, is trying to assess the usefulness of RQ for optimizing nutrition in patients treated in the ICU.

Methodology:

Study group:

This will be a randomized study with a study group and a control group in patients treated in the ICU. All patients participating in the study are patients who, at the time of qualification, are mechanically ventilated and treated in the ICU. These will be patients of both sexes, aged 18-85 years. The control group will be fed under the supervision of indirect calorimetry and REE, in accordance with current ICU nutrition guidelines. In the study group, nutritional preparations will be additionally systematized and selected for each patient depending on their RQ value, and caloric requirements will be controlled by indirect calorimetry and REE, as in the control group. Regular assessments of albumin, total protein, total cholesterol, LDL, HDL, iron, glycemia, Na⁺, K⁺, and triglycerides will be conducted, collected along with the routine test package. In addition, typical endpoints for patients treated in the ICU will be assessed, such as length of stay in the ICU, length of mechanical ventilation, number of days without a ventilator, 28-day survival, and survival to hospital discharge.

Expected duration of the study: October 2024 to October 2026 (2 years)

Conditions for inclusion in the study: patients > 18 years of age, treated in the ICU, mechanically ventilated, covered by universal health insurance

Conditions for exclusion from the study: ECMO therapy, the need for mechanical ventilation with an oxygen concentration in the breathing mixture FiO₂ > 60%, patients breathing independently without the

aid of a ventilator, critically ill patients who are not expected to survive the next 48 hours, pregnant women, patients < 18 years of age or > 85 years of age

Reasons for discontinuing the study:

- a. if, during the course of the study, there are clear indications that one of the groups will experience or worsen final outcomes such as mortality, 28-day mortality, length of stay in the ICU – which would suggest a clear advantage of one of the chosen strategies, along with an increase in the number of patients included in the study, a regular analysis of the current effects of both strategies will be conducted,
- b. the patient develops hypersensitivity/intolerance to nutritional preparations, with no possibility of switching to another preparation used in the study,

Planned scope of procedures and options for obtaining informed consent:

All preparations used in the study are tested, registered, and routinely used in enteral and parenteral treatment in the ICU. Similarly, the use of indirect calorimetry is currently the “gold standard” of treatment in the ICU and is part of standard practice in the ICU. The devices used for indirect calorimetry automatically calculate the respiratory quotient (RQ) without additional therapeutic interventions. The laboratory test results that will be used in the study are also part of standard therapy in the ICU, will be performed along with routine tests, and will not require additional invasive interventions. The work will consist solely of systematizing existing therapies based on routinely measured RQ values. Therefore, investigators believe that it is possible to waive the requirement to obtain informed consent to participate in the study. Furthermore, in the case of this group of patients, i.e., unconscious, mechanically ventilated, and treated in the ICU, given the narrow time frame for

inclusion in the study, obtaining the consent of the patient or the competent court prior to inclusion in the study seems impracticable.

Expected results and their planned subsequent use:

In patients from the control group, investigators should achieve faster stabilization of nutritional parameters and fewer episodes of underfeeding and overfeeding. This should translate into improved endpoints such as mortality, length of stay in the ICU, and shorter mechanical ventilation time. In addition, the systematization and algorithms for the use of nutritional products developed during the study can be further used in our department and other departments in the country and around the world.