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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?

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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 aims to assess the usefulness of RQ for optimizing nutrition in patients treated in the ICU.

Methodology:

Study group: This will be a single-center, prospective, randomized controlled study involving mechanically ventilated ICU patients aged 18–85 years, with an anticipated need for invasive mechanical ventilation for more than 48 hours. The control group will receive nutritional therapy guided by indirect calorimetry and REE, in accordance with current ICU nutrition guidelines. In the study group, nutritional formulations will additionally be selected according to RQ values (<0.80, 0.80–0.85, and >0.85), while caloric requirements will be determined using REE, as in the control group.

Laboratory parameters related to nutritional and metabolic status will be assessed regularly as part of routine ICU care.

The primary outcome will be 28-day ventilator-free days (VFD), defined as the number of days alive and free from invasive mechanical ventilation during the first 28 days after randomization. Patients who die before day 28 or remain invasively ventilated throughout this period will be assigned 0 VFD. Secondary outcomes will include 28-day survival, survival to ICU and hospital discharge, ICU length of stay, ventilator-associated pneumonia, illness severity scores, and laboratory parameters.

The planned maximum sample size is 240 participants (120 per group). The primary analysis will follow the intention-to-treat (ITT) principle, estimating the between-group difference in mean VFD using a linear model with HC3 robust standard errors. The Mann–Whitney U test will be used as a sensitivity analysis. An additional supportive analysis will include participants mechanically ventilated for more than 48 hours.

Expected duration of the study: October 2024 to September 2027

Conditions for inclusion in the study: patients aged ≥18 and ≤85 years, treated in the ICU, receiving invasive mechanical ventilation with an anticipated need for mechanical ventilation for more than 48 hours, and covered by universal health insurance.

Conditions for exclusion from the study: ECMO therapy, FiO2 >60%, spontaneous breathing without invasive mechanical ventilation, critically ill patients not expected to survive the next 48 hours, pregnancy, age <18 or >85 years, prisoners transferred from penal institutions, and significant gastrointestinal disorders preventing standard nutritional therapy.

Reasons for discontinuing the study:

a. Two formal interim efficacy analyses are planned after primary-outcome data are available for approximately 80 and 160 randomized participants. A Lan–DeMets alpha-spending function approximating O'Brien–Fleming boundaries will be used to control the overall two-sided type I error rate at 0.05. The study may be terminated early for compelling efficacy or important safety concerns. No formal early stopping for futility is planned.

b. The assigned nutritional intervention may be discontinued in the event of hypersensitivity or intolerance to nutritional formulations, inability to continue study-directed nutrition, or other clinically justified reasons. All randomized participants will remain included in the primary ITT analysis regardless of intervention discontinuation.

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. The Bioethics Committee approved enrollment without obtaining prospective informed consent. 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 study group, investigators should achieve faster stabilization of nutritional parameters and fewer episodes of underfeeding and overfeeding. This may translate into an increase in 28-day ventilator-free days (VFD), with potential improvements in secondary clinical outcomes, including mortality and ICU length of stay. 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.