PREVALENCE OF SARCOPENIA IN PATIENTS ADMITTED TO THE ICU AND ITS PROGRESSION DURING HOSPITALIZATION

NCT number

11/03/2025

1. General Information

1.1. Study Identification

Title: PREVALENCE OF SARCOPENIA IN PATIENTS ADMITTED TO THE ICU AND ITS PROGRESSION DURING HOSPITALIZATION

Protocol Code or Identification Number: Version 1. 03/11/2025

1.2. Sponsor Identification

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1.3. Identification of the Principal Investigators at Participating Centers

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2. Justification

Both the type of pathology and the average age of patients admitted to an Intensive Care Unit (ICU) have significantly changed in recent years. Currently, admissions include patients classified as "Very Old Patients" (>80 years old). Sarcopenia is defined as muscle failure characterized primarily by decreased strength rather than reduced muscle mass.

Population studies indicate that muscle function deficits are an increasing concern, especially in older adults but also in younger adults, particularly in association with obesity. The prevalence of sarcopenia is projected to increase by 70% by 2045. Currently, literature reports prevalence rates of 8–36% in individuals under 60 years old and 10–27% in those over 60, with a rate of 5–13% among those aged 60–70. Sarcopenia is associated with an increased risk of falls, fractures, physical dysfunction, and mortality.

Given its prevalence in the general population, it is expected that ICU patients also present some degree of sarcopenia, which could be related to their subsequent clinical course. Additionally, ICU patients—especially those with shock and/or undergoing mechanical ventilation—may develop ICU-acquired weakness (ICU-AW). This syndrome is defined as weakness and muscle dysfunction secondary to critical illness, unrelated to other etiologies (such as myasthenia gravis, amyotrophic lateral sclerosis, or Guillain-Barré syndrome).

Several factors contribute to neuromuscular dysfunction in critically ill patients. It typically presents symmetrically, affects respiratory and limb muscles (more pronounced in proximal muscles), and spares facial muscles. Pathophysiologically, it involves an imbalance between increased muscle atrophy and

reduced function. Muscle atrophy is caused by a catabolic state and immobilization. Studies show that muscle mass loss can exceed 10% within the first week of ICU stay.

Muscle dysfunction results from structural changes (necrosis, inflammation, fibrosis), neuronal damage, altered microcirculatory perfusion, mitochondrial dysfunction with increased free radicals, insufficient autophagy, and disruptions in membrane and sodium channel function—leading to impaired muscle excitability and contractility.

Kangalgil M et al. studied the relationship between pre-ICU nutritional status and risk of muscle mass loss in critically ill patients. A meta-analysis of 10 cohort studies concluded that sarcopenia at ICU admission is associated with increased mortality in patients with sepsis.

Diagnosing ICU-AW requires the assessment of muscle strength, which needs patient cooperation. The most commonly used tool for muscle strength assessment in critically ill patients is the **Medical Research Council (MRC) scale**, with scores <48 indicating significant myopathy and <36 severe myopathy.

For ventilated patients, respiratory parameters such as **maximum inspiratory pressure** (<-25 cmH_2O) can indicate myopathy.

Therefore, it is essential to consider both muscle function and physical capacity—not just muscle mass quantity—when assessing sarcopenia risk upon ICU admission.

2.1. Relevant Bibliography

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3. Study Objectives and Purpose

The primary objective is to describe the prevalence of sarcopenia at the time of ICU admission in patients expected to require mechanical ventilation (MV) for more than 48 hours.

Secondary objectives:

1. Detect patients who develop ICU-acquired weakness (ICU-AW) and/or prolonged weaning from mechanical ventilation, defined as failure to successfully discontinue mechanical ventilation after three attempts or after 7 days from the first spontaneous breathing trial.

2. Detect the occurrence of other complications during hospitalization, such as refeeding syndrome or increased prevalence of insulin resistance.

3.1. Primary and Secondary Variables

Data will be collected anonymously using a REDCap database. Anthropometric variables including age, sex, weight, and body mass index (BMI) will be recorded as primary indicators of body composition. Blood parameters from routine admission tests will be analyzed, including hemoglobin (Hb), leukocytes, creatinine, and urea. Prealbumin will be recorded as a sensitive nutritional marker due to its short half-life. Iron metabolism will be assessed via ferritin, serum iron, and transferrin saturation index (TSI). Vitamin B12, folic acid, and vitamin D levels, as well as minerals such as phosphorus and magnesium, will also be measured. A lipid profile including total cholesterol, LDL, HDL, and triglycerides will be documented.

Muscle function and body composition will be assessed using:

- The SARC-F questionnaire, a simple tool to screen for sarcopenia;

- Bioelectrical impedance analysis (BIA), which quantifies muscle mass, fat, and hydration status;
- Quadriceps ultrasound, providing data on the Y-axis (muscle morphology) and cross-sectional area (muscle mass);
- The Medical Research Council (MRC) scale, used to evaluate muscle strength.

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4. Study Design

This is a prospective, observational, and descriptive study conducted at the Intensive Care Medicine Department of Hospital Mútua de Terrassa, from May 2025 to December 2025. The study will include medical or surgical patients over 18 years of age admitted to the ICU with an anticipated need for mechanical ventilation for more than 48 hours.

Informed consent will be requested from the patient or their closest relative for data collection. Anthropometric and nutritional values will be monitored weekly.

With the support and collaboration of the Endocrinology and Nutrition Departments, muscle mass will be assessed within the first 24 hours of ICU admission using:

1. The SARC-F score (Annex 1), considered positive for symptomatic sarcopenia if ≥4;
2. Ultrasound of the rectus femoris muscle (Venue™ Ultrasound, GE HealthCare) performed by the investigators;
3. Bioelectrical impedance analysis (BIA 101 BIVA® PRO – Akern).

Follow-up ultrasound will be performed on day 7 and again at ICU discharge, along with repeat BIA. Data collectors will be trained by a femoral ultrasound expert.

To diagnose ICU-AW, patients will be monitored throughout their ICU stay. The MRC score (Annex 2) will be recorded at the start of weaning and followed until discharge. ICU-AW will be classified as significant myopathy (MRC <48) and severe myopathy (MRC <36).

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5. Participant Selection

All patients over 18 years of age, medical or surgical, admitted to the ICU with anticipated mechanical ventilation >48 hours who voluntarily consent to participate will be included.

5.1. Inclusion Criteria

- Age >18 years

- Anticipated mechanical ventilation >48 hours

5.2. Exclusion Criteria

- Refusal to participate
- Mechanical ventilation <48 hours
- Do-not-resuscitate (DNR) orders or therapeutic limitations at admission

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6. Study Treatment and Timeline

Patient recruitment will take place from May 2025 to December 2025. Patients will be assessed within the first 48 hours of ICU admission by the research team. If inclusion criteria are met, the variables mentioned above will be collected on the first day, on day 7, and on day 14 of ICU stay.

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7. Statistics

7.1. Sample Size

An estimated 20 patients per month will be recruited, totaling around 120 patients over 6 months.

7.2. Statistical Analysis

Descriptive analysis will include measures of central tendency and dispersion. Group comparisons will use paired Student's t-test for parametric variables, or Mann-Whitney/Wilcoxon tests for non-parametric data. For comparisons of more than two groups, ANOVA or Kruskal-Wallis tests will be used, depending on normality. Linear or logistic regression models will be applied as appropriate.

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8. Ethics and Legal Considerations

The study will comply with the Declaration of Helsinki (75th WMA General Assembly, Finland, November 2024).
It will be conducted in accordance with the protocol and applicable legal requirements per Law 14/2007 of July 3, on biomedical research.

9. Data Processing, Record Storage, and Confidentiality

Hospital Universitari Mútua Terrassa (CIF G66886144) is the data controller. The processing, communication, and transfer of participants' personal data will comply with Regulation (EU) 2016/679 and Organic Law 3/2018 on data protection and digital rights.

Study data will be pseudonymized using a code and will not include any directly identifying information. Only the study physician and authorized collaborators will be able to link this code to clinical records. Identity will not be accessible unless required due to a medical emergency or legal obligation. Health authorities, the Ethics Committee, and the study sponsor's authorized personnel may access the data for verification, always respecting confidentiality.

Only coded data will be transferred to third parties or other countries, without direct identifiers (e.g., name, address, ID). Transfers outside the EU will be subject to contracts or safeguards established by data protection authorities.

Participants have rights to access, rectify, delete, limit, or port their data. For exercising these rights or more information, contact the principal investigator or the Data Protection Officer at dpd@mutuaterrassa.es. You may also contact the Spanish Data Protection Agency if not satisfied.

Previously collected data will not be deleted upon study withdrawal, to ensure research validity, but no new data will be collected from that point. Data will be retained for at least 25 years post-study. Thereafter, personal data may only be used for healthcare or further research, if consent is provided and ethically and legally allowed.

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10. Funding

This study has no external funding.

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11. Publication Policy

There is an express commitment to publish the results of the study regardless of whether the results are positive or negative.

ANNEX 1: SARC-F SCORE

Strength: How much difficulty do you have lifting and carrying 5 kg?

- None – 0
- Some – 1

- A lot or unable – 2

Assistance in walking: How much difficulty do you have walking across a room?

- None – 0
- Some – 1
- A lot/use of aids or unable – 2

Getting up from a chair: How much difficulty do you have transferring from a chair or bed?

- None – 0
- Some – 1
- A lot or unable without help – 2

Climbing stairs: How much difficulty do you have climbing a flight of 10 stairs?

- None – 0
- Some – 1
- A lot or unable – 2

Falls: How many times have you fallen in the past year?

- None – 0
- Less than 3 times – 1
- 4 or more times – 2

ANNEX 2: MRC SCALE

- **Grade 5:** Normal muscle strength against full resistance.
- **Grade 4:** Reduced strength; muscle contraction can still overcome resistance.

- **Grade 3:** Strength reduced to the point that movement is only possible against gravity, not resistance.

- **Grade 2:** Active movement not against gravity (e.g., flexing the elbow with the arm supported horizontally).

- **Grade 1:** Visible or palpable muscle contraction without movement.

- **Grade 0:** No contraction detected.