



ACCUMULATE STUDY

ImpACt of very high protein Content enteral nUtrition formulas on protein metabolism and residual gastric volume in critically ill MUltiple trAuma paTiEnts

– ACCUMULATE trial –

NCT: 05647135

December 1, 2022

ANNEX 7**INFORMED CONSENT**

You are kindly requested to read this form carefully and ask any questions regarding your participation in the study you have been invited to, before agreeing to participate. For enrollment in this study, it will be necessary for you to give your final written consent.

1. **Description of the Research:** You are invited to participate in a research study aimed at investigating the influence of nutritional support on muscle mass status. Additionally, by adhering to the study, you will contribute substantially to the communication of important data about the nutritional status of patients in intensive care within the Romanian population. The present study, titled "ImpACt of Very High Protein Content Enteral Nutrition Formulas on Critically Ill Multiple Trauma Patients (ACCUMULATE)," is of great current importance as specialized reports indicate that adequate nutritional therapy improves patient prognosis. Patients included in the study must agree to the use of data available in observation sheets, without requiring additional interventions or laboratory analyses.
2. **Presentation of Risks:** There are no risks.
3. **Confidentiality:** All personal data will be kept strictly confidential. The results derived from this study will be published for scientific purposes but will not include your name or any other personal data. Cohort data will be communicated with all the scientific implications derived from the evaluations conducted, but these will be in the form of professional constants and variables, without personal annotations or direct references to the subject. Any data provided about you will be kept confidential, and the only persons who will have access to your identity are the medical staff involved in conducting the study. The necessary information for the study may be made available to the institution hosting the research (Emergency Clinical Hospital Bucharest), the local Ethics Committee, in compliance with current legislation and regulations. By signing this form, you agree to these conditions. Confidentiality is limited if information is identified that could endanger public health. After the study is completed, the collected biological samples will be destroyed.
4. **Compensations:** There are no financial or material rewards for your participation in this study. We do not anticipate situations that might require emergency care due to your participation in this study. If you wish to withdraw from the study, this can be done at any time without suffering any consequences from this decision. The proposed and conducted investigations within this study are free of charge for the patient.
5. **Volunteering and Withdrawal:** You are free to decide whether you agree to participate in this study. If you do not agree to participate in the study, you will not lose any benefits to which you are entitled. You are free to withdraw from the study at any time without penalties. There are no medical consequences for your withdrawal from the study.
6. **Contacts:** You have the right to ask any questions regarding this study at any time.

Contact Person: Dr. Cristian Cobilinschi – cristian.cobilinschi@umfcd.ro



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AUTHORIZATION: "I have read and understood this consent form and agree to participate in the described study voluntarily."

Patient's Name:

Legal Representative:

Name:

Signature:

Date:

Contact Phone: