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

– ACCUMULATE trial -

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December 1, 2022

Sample size calculation:

- Expected difference ($\Delta\Delta$) = 0.4 g/kg BW
- Standard deviation ($\sigma\sigma$) = 0.5 g/kg BW
- Significance level ($\alpha\alpha$) = 0.05
- Power ($1-\beta1-\beta$) = 0.80

- With an expected difference of 0.4 g/kg BW and a standard deviation of 0.5, a minimum sample size of 25 per group is required.

- To ensure robustness and account for drop-outs and variability, targeting at least 28 participants per group is recommended.

Statistical Analysis:

1. **Descriptive Statistics:**
   - Summary statistics (mean, standard deviation, median, interquartile range) will be provided for all continuous variables. Frequencies and percentages will be provided for categorical variables.
2. **Primary Outcome Analysis:**
   - Differences in protein and calorie intake between the groups at day 5 and day 10 will be analyzed using independent t-tests or Mann-Whitney U tests, depending on the data distribution.
   - Differences in residual gastric volume between the groups at day 5 and day 10 will be analyzed using independent t-tests or Mann-Whitney U tests.
3. **Secondary Outcome Analysis:**
   - Changes in quadriceps rectus femoris thickness over time will be analyzed using repeated measures ANOVA or mixed-effects models.
   - Differences in body composition parameters (Fat-Free Mass, Total Body Water, Phase Angle) will be analyzed using paired t-tests or Wilcoxon signed-rank tests for within-group comparisons and independent t-tests or Mann-Whitney U tests for between-group comparisons.
   - Differences in plasmatic levels of prealbumin and C-reactive protein will be analyzed using independent t-tests or Mann-Whitney U tests.
   - Differences in handgrip strength will be analyzed using paired t-tests or Wilcoxon signed-rank tests for within-group comparisons and independent t-tests or Mann-Whitney U tests for between-group comparisons.
4. **Missing Data:**
   - Missing data will be handled using multiple imputation or other appropriate methods. Sensitivity analyses will be conducted to assess the robustness of the results.
5. **Statistical Software:**
   - All analyses will be performed using statistical software such as SPSS, GraphPad