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A Randomized Controlled Pilot Trial of Indomethacin in Acute Pancreatitis

NCT02692391

Statistical Analysis Plan

The sample size calculation was based on our prospective observational data on the incidence of SIRS among hospitalized patients with AP and on the assumption that a mean SIRS score reduction of 0.5 with a standard deviation of 0.64 was clinically meaningful. We estimated that a sample size of 42 patients was needed to detect a difference of 0.5 in the SIRS change (baseline to 48h) between the indomethacin and placebo arms, with a power of 80% and a one-sided alpha of 0.05.

Descriptive statistics are reported as absolute values (percentage), mean ± standard deviation (SD), or median (interquartile range [IQR]), as appropriate. For the analysis of the primary endpoint, we used a two-sided Wilcoxon rank-sum test to analyze the difference in the change of SIRS scores between the treatment groups. Missing data of the primary outcome was handled using the last observation carried forward imputation method. Comparisons of baseline characteristics and secondary endpoints were evaluated using chi-square or Fisher's exact tests for categorical data and t–test or Wilcoxon rank sum test for continuous data, as appropriate. Kaplan-Meier methodology was used to estimate the overall risk of organ failure in each treatment group. The log-rank test was used to test the difference in risk of organ failure between treatment arms. Patients were followed up until date of organ failure or censoring. All analyses were performed according to the intention-to-treat principle. Per-protocol analysis was also performed. Statistical significance was defined as $P<0.05$.

Firgure 1: Enrollment, Randomization and Retention of Study Participants.