

A Double-Blind, Randomized Control Trial of Rapidly Infused High Strong Ion Difference Fluid versus Hartmann's solution on Acid-Base Status in Sepsis and Septic Shock Patients in the Emergency Department Hospital Pulau Pinang

Protocol number: ED-HPP-1701 (15th Jan 2017)

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STATISTICAL ANALYSIS

The sample size was calculated based on the following: α value 0.05, power of 0.95 and standard deviation of 0.05. It was powered to detect a 0.03 difference in the post resuscitation blood pH between 2 study fluids. The calculated sample size was 73 patients each arm with total 146 patients. Considering drop-out rate of 10%, total sample size is 162 (81 patients each arm). The significance level was set at p-value less than 0.05.

The mean difference of pre- and post-resuscitation blood pH level, bicarbonate level, difference in lactate level, incidence of acute kidney injury, all-cause mortality at 30 days, length of stay between 2 groups were analyzed using different test depending on whether the means were normally distributed (independent T-test) or non-normally distributed (Mann-Whitney Test). All the data are carefully assessed for skewness and Kurtosis, the sample was assumed not normally distributed if the Kurtosis value is more than 3.29.