Randomized Controlled Trial of Inferior Vena Cava Ultrasonography in the Management and Disposition of Pediatric Patients Undergoing Evaluation for Sepsis and Dehydration
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NCT02568189
Document Date: 5-2-24

Gastroenteritis Statistical Plan

We calculated the sample size required to provide more than 80% power (with a two-sided alpha level of 0.05) to detect an absolute difference of 15% in PO vs. IV rehydration or more between groups. We estimated a sample size of 200 patients for the gastroenteritis section of the study.

Enrolled Patients are to be randomized to immediate versus delayed US assessment of the IVC in patients aged 0-21 years who presented to an emergency department with vomiting requiring ondansetron or with diarrhea possibly requiring IV rehydration. Patients enrolled were randomized to assessment of dehydration by clinical exam plus US (immediate) or clinical exam alone and then US 15 minutes later (delayed). Clinical dehydration scores were recorded prior to IVC US. Decision to treat with IV versus PO rehydration, pre-test and post-test probabilities were recorded before and after US. Primary outcomes included IV versus PO rehydration based on intent-to treat principle; secondary outcomes included median total ED length of stay (EDLOS; triage time to disposition) time failure of PO rehydration, and disposition (ED discharge vs admission). All outcomes between groups were compared by using a Pearson chi-squared test. The alpha level was set at .05 for all analyses, 95% CIs were calculated, and all comparisons were two tailed. Data analysis was performed with the use of SPSS 20.0 (IBM).

We calculated the sample size required to provide more than 80% power (with a two-sided alpha level of 0.05) to detect an absolute difference of 15% more more between arms in the number of patients receiving antibiotics with 60 minutes between groups. We estimated a sample size of 200 patients for the sepsis section of the study.

Sepsis Statistical Plan

Enrolled Patients are to be randomized to immediate versus delayed US assessment of the IVC in patients aged 0-21 years who presented to an emergency department with a STOP SEPSIS triage alert and clinical concern for sepsis. Patients enrolled were randomized to assessment of sepsis by clinical exam plus US (immediate) or clinical exam alone and then US 15 minutes later (delayed). Pre-test probability of sepsis were recorded prior to IVC US. Decision to initial sepsis protocol/pathway, pre-test and post-test probabilities were recorded before and after US. Primary outcomes included proportion of patients receiving antibiotics within 60 minutes based on intent-to treat principle; secondary outcomes include median total ED length of stay (EDLOS; triage time to disposition), time to secured vascular access, and vasopressor use. All outcomes between groups were compared by using a Pearson chi- squared test. The alpha level was set at .05 for all analyses, 95% CIs were calculated, and all comparisons were two tailed. Data analysis was performed with the use of SPSS 20.0 (IBM).