

Trimethoprim-sulfamethoxazole vs Levofloxacin as Targeted Therapy for *Stenotrophomonas maltophilia* Infections: A Retrospective Cohort Study

NCT ID not yet assigned

Document date: November 18, 2020

Statistical Plan

A propensity score will be generated using clinically-relevant patient, infection, treatment and center related variables. These include age, sex, immunocompromised status, baseline SOFA score, Elixhauser comorbidity index, culture site, polymicrobial infection, ICU stay, mechanical ventilation, vasopressor use, year category, academic status, urban/rural qualification, geographic region and bed capacity. The primary outcome for analysis will be in-hospital mortality or discharge to hospice. This will be analyzed using logistic regression and presented as an adjusted odds ratio. The secondary outcome is hospital length of stay, where mortality will be censored at the longest length of stay and analyzed using Cox model. Predefined subgroups for analysis are based on site of infection (lower respiratory tract, blood stream infection), SOFA score (high/low) and whether the patient was on mechanical ventilation within a window of -3 to + 3 days of culture drawn (yes/no). Sensitivity analyses will be performed on those variables that could potentially affect outcomes to ensure robustness of data: polymicrobial culture growth, polymicrobial culture with treatment other than agent active against *Stenotrophomonas maltophilia*, receipt of empiric therapy (day -2 to day 0 of culture positivity), diagnosis code for pneumonia not present on admission and imputed susceptibility. We plan to use overlap weighting to ensure balance between both groups without truncation of the study sample. Weighted regression analysis may be performed to mitigate potential residual confounding. All statistical analyses will be performed using *R* or *SAS*.