Supplemental Digital Content 8

Sample Size Calculation

Although not intended for formal statistical comparisons, the sample size calculation was based on a 95% probability of observing at least 1 AE with an underlying incidence rate of at least 3% in ≥1 patient of 120 treated with ceftazidime-avibactam in the combined safety analysis sets of the 2 pediatric studies in patients with cIAI (NCT02475733) and patients with cUTI (NCT02497781).[1] Based on this, target enrollment for the current study was 80 evaluable patients who received ≥72 hours of treatment (9 doses) with a 3:1 randomization ratio: 60 treated with ceftazidime-avibactam plus metronidazole and 20 with meropenem.

1. Bradley J, Roilides E, Broadhurst H, et al. Safety, efficacy and pharmacokinetics of ceftazidime-avibactam (CAZ-AVI) versus cefepime in hospitalised paediatric patients with complicated urinary tract infection (cUTI). In: *European congress of clinical microbiology and infectious diseases*. Madrid, Spain. 2018. O1124.