Safety and Efficacy of Ceftolozane/Tazobactam Plus Metronidazole Versus Meropenem From a Phase 2, Randomized Clinical Trial in Pediatric Participants With Complicated Intra-abdominal Infection

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Supplemental Digital Content 3

Subgroup Analyses of Participants Achieving Clinical Cure Response at the TOC Visit (MITT Population)

Clinical cure by subgroup, n/N1 (%)	C/T + MTZ (N=70)	MEM + placebo (N=21)
Sex		
Male	39/47 (83.0)	6/6 (100.0)
Female	17/23 (73.9)	15/15 (100.0)
Region		
North America	20/26 (76.9)	7/7 (100.0)
Europe	33/37 (89.2)	13/13 (100.0)
South America	0/1 (0)	–
Africa	2/4 (50.0)	–
Asia/Pacific	1/2 (50.0)	1/1 (100.0)
Duration of IV study treatment		
<7 days	33/43 (76.7)	16/16 (100.0)
≥7 days	23/27 (85.2)	5/5 (100.0)
Number of abscesses		
Single	16/20 (80.0)	5/5 (100.0)
Multiple	40/50 (80.0)	16/16 (100.0)
Peritonitis type		
Local	13/18 (72.2)	9/9 (100.0)
Diffuse	24/27 (88.9)	6/6 (100.0)
Missing	19/25 (76.0)	6/6 (100.0)
Procedure type		
Percutaneous	2/2 (100.0)	0
Laparoscopic	36/44 (81.8)	11/11 (100.0)
Open	16/20 (80.0)	9/9 (100.0)
Other	2/3 (66.7)	1/1 (100.0)
Missing	0/1 (0)	0

Prior antibacterial agent use		
Yes	53/67 (79.1)	21/21 (100.0)
No	3/3 (100.0)	0
Site of infection		
Appendix	52/64 (81.3)	21/21 (100.0)
Nonappendix	4/6 (66.7)	0
Bacteremia at baseline		
Yes	2/2 (100.0)	0
No	54/68 (79.4)	21/21 (100.0)
Number of baseline pathogens		
Polymicrobial	31/38 (81.6)	14/14 (100.0)
Monomicrobial	22/26 (84.6)	5/5 (100.0)
Missing	3/6 (50.0)	2/2 (100.0)

C/T, ceftolozane/tazobactam; IV, intravenous; MEM, meropenem; MITT, modified intent-to-treat; MTZ, metronidazole; TOC, test of cure.
N1=Number of participants in the specific subgroup. Percentages were calculated as 100 × (n/N1).