

Table 1 Summary of patient characteristics in the blinded midazolam and blinded placebo arms for the primary analysis cohort, external validation cohort and the total study.

Summary Statistics	Primary analysis (Midazolam)	Primary analysis (Placebo)	External Validation (Midazolam)	External Validation (Placebo)	Total
Age (n [%])					
A. 0-30 days	6 (16)	7 (17)	5 (22)	4 (21)	22 (18)
B. 30 days - 2 years	21 (57)	24 (57)	14 (61)	13 (68)	72 (60)
C. 2 - 18 years	10 (27)	11 (26)	4 (17)	2 (11)	27 (22)
Sex (n [%])					
Male	23 (62)	23 (55)	15 (65)	12 (63)	73 (60)
Female	14 (38)	19 (45)	8 (35)	7 (37)	48 (40)
Diagnosis (n [%])					
Viral	17 (46)	25 (60)	10 (43)	9 (47)	61 (50)
Respiratory Insufficiency					
Pneumonia	6 (16)	3 (7)	4 (17)	4 (21)	17 (14)
Other	14 (38)	14 (33)	9 (39)	6 (32)	43 (36)
Patient characteristics (median [lower quartile, upper quartile])					
Weight (kg)	4.60 (3.60, 12.00)	5.69 (3.90, 10.8)	4.40 (3.79, 8.45)	4 (3.50, 5.25)	5.00 (3.70, 10.0)
PRISM II	16 (12, 20)	15 (13, 23)	15 (11, 23.50)	16 (12.5, 24)	16 (12, 22)
PIM 2 (%)	3.16 (2, 7)	5.02 (2.26, 10.3)	1.95 (1.06, 6.48)	1.85 (1.30, 7.35)	3.61 (1.62, 7.80)
PELOD	11 (11, 13)	11 (4, 12.75)	11 (11, 20)	11 (10.50, 17)	11 (11, 20)
Study Specific characteristics (median [lower quartile, upper quartile])					
Duration of First Intubation (Days)	4 (3, 6)	5 (4, 7)	5 (3, 7)	6 (4.50, 7)	5 (4, 7)
Length of Stay in P-ICU (Days)	8 (6, 14)	7.50 (5.25, 12.50)	7 (5, 15.50)	7 (5.50, 13)	8 (5, 14)
Safety Screens					
Passed	4 (3, 5)	3 (2, 4)	3 (2, 5.50)	3 (1, 4)	3 (2, 5)
Failed	0 (0, 2)	0 (0, 1)	0 (0, 0.50)	0 (0, 1)	0 (0, 1)
Total	4 (3, 7)	4 (3, 5)	4 (3, 6)	5 (4, 6)	4 (3, 6)