

Secondary efficacy outcome 6: Insulin requirements

Table 6.6-20: Insulin requirements – Completeness of data (ITT)

Analysis status	Reason	CSII	MDI	Total
Included	Included	87 (60.4%)	64 (43%)	151 (51.5%)
Excluded	No dose data	56 (38.9%)	76 (51%)	132 (45.1%)
	No dose data and weight not recorded	0 (0%)	2 (1.3%)	2 (0.7%)
	WD from study prior to 12 months	1 (0.7%)	5 (3.4%)	6 (2%)
	Weight not recorded	0 (0%)	2 (1.3%)	2 (0.7%)

Table 6.6-21: Insulin requirements – Results (ITT)

strata	Insulin requirements (Units/kg/day)	CSII	MDI	Total	Least Squares Mean Difference between treatment groups (CSII-MDI) across all age-groups	p-value
7mths - < 5yrs	Missing	0	0	0	0.1 (0, 0.2)	0.01
	N	24	13	37		
	Mean (SD)	0.7 (0.2)	0.7 (0.1)	0.7 (0.2)		
	Median (IQR)	0.8 (0.6, 0.8)	0.6 (0.6, 0.7)	0.7 (0.6, 0.8)		
	(Min, Max)	(0.3, 1.2)	(0.4, 0.9)	(0.3, 1.2)		
5yrs - <12yrs	Missing	0	0	0		
	N	45	38	83		
	Mean (SD)	0.6 (0.2)	0.6 (0.3)	0.6 (0.3)		
	Median (IQR)	0.6 (0.5, 0.8)	0.6 (0.4, 0.7)	0.6 (0.4, 0.8)		
	(Min, Max)	(0.2, 1.2)	(0, 1.2)	(0, 1.2)		
12yrs - <16yrs	Missing	0	0	0		
	N	18	13	31		
	Mean (SD)	0.8 (0.2)	0.5 (0.4)	0.7 (0.3)		
	Median (IQR)	0.8 (0.6, 0.9)	0.7 (0, 0.8)	0.7 (0.5, 0.9)		
	(Min, Max)	(0.4, 1.2)	(0, 0.9)	(0, 1.2)		
Overall	Missing	0	0	0		
	N	87	64	151		
	Mean (SD)	0.7 (0.2)	0.6 (0.3)	0.6 (0.3)		
	Median (IQR)	0.7 (0.5, 0.8)	0.6 (0.4, 0.8)	0.6 (0.5, 0.8)		
	(Min, Max)	(0.2, 1.2)	(0, 1.2)	(0, 1.2)		

Note: The Estimated G matrix was not positive definite which indicates that the variance component in the RANDOM statement (site) are estimated to be zero so were removed from the model.