

Table 15.3.1.2
Ratio between the highest value post-surgery and baseline for serum creatinine - supplementary analysis
Per-protocol set

		Treatment		
		Placebo (N=94)	Ilofotase Alfa (N=109)	Total (N=203)
Highest sCreat Value Post-surgery [umol/L]	n	93	109	202
	Mean (SD)	153.287 (71.619)	145.718 (66.613)	149.202 (68.893)
	Median	132.000	126.410	129.535
	Q ₁ , Q ₃	111.390, 167.000	107.850, 159.000	110.000, 164.430
	Min, Max	75.14, 466.76	70.72, 433.17	70.72, 466.76
Baseline sCreat Value [umol/L]	n	94	109	203
	Mean (SD)	119.956 (24.334)	119.207 (27.116)	119.554 (25.804)
	Median	116.690	114.000	114.920
	Q ₁ , Q ₃	106.080, 129.070	101.000, 133.000	103.000, 132.600
	Min, Max	64.53, 209.00	66.00, 208.63	64.53, 209.00
Ratio Highest sCreat Value / Baseline sCreat Value	n	94	109	203
	Mean (SD)	1.271 (0.504)	1.211 (0.422)	1.239 (0.462)
	Median	1.115	1.100	1.110
	Q ₁ , Q ₃	0.990, 1.330	0.970, 1.250	0.990, 1.270
	Min, Max	0.79, 3.62	0.74, 3.09	0.74, 3.62

Highest sCreat value post-surgery of Day 1, 2, 3, 4, and 5.

Patient 4100010008 died after the second IP administration and prior to Day 5, therefore the 'Ratio Highest sCreat Value / Baseline sCreat Value' was imputed with 1.25 (ICE 3) and no 'Highest sCreat Value Post-surgery' is given.

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ANCOVA
Individual least squares means

Treatment	N	LS Means	Standard Error	95% Wald Confidence Interval
Placebo	94	1.349	0.061	[1.227; 1.470]
Ilofotase Alfa	109	1.279	0.055	[1.171; 1.388]

Difference in least squares means

Treatment	Difference in LS Means	95% Wald Confidence Interval	P-Value (Two-Sided)
Ilofotase Alfa - Placebo	-0.069	[-0.197; 0.059]	0.2871

Parameter estimates

Parameter	Estimate	Standard Error	P-Value (Two-Sided)
Intercept	1.559	0.292	<.0001
Treatment: Ilofotase Alfa	-0.069	0.065	0.2871
Pre-operative baseline sCreat value	-0.001	0.002	0.7427
Baseline eGFR: > 45 mL/min/1.73m2	-0.204	0.114	0.0762
Type of surgery: CABG with 3 or more distal anastomoses	-0.078	0.067	0.2477

Covariates = pre-operative baseline sCreat value, baseline eGFR (reference = ≤ 45 mL/min/1.73m2), and planned type of surgery (reference = CABG combined with valve surgery).