

Final analysis

Table 15.3.1.3

Ratio between the highest value post-surgery and baseline for serum creatinine - sensitivity analysis (with additional covariates - CPB-pump time, cross-clamp time)

Full analysis set

ANCOVA**Individual least squares means**

Treatment	N	LS Means	Standard Error	95% Wald Confidence Interval
Placebo	95	1.347	0.061	[1.227; 1.467]
Ilofotase Alfa	109	1.279	0.055	[1.170; 1.387]

Difference in least squares means

Treatment	Difference in LS Means	95% Wald Confidence Interval	P-Value (Two-Sided)
Ilofotase Alfa - Placebo	-0.069	[-0.196; 0.059]	0.2891

Parameter estimates

Parameter	Estimate	Standard Error	P-Value (Two-Sided)
Intercept	1.600	0.309	<.0001
Treatment: Ilofotase Alfa	-0.069	0.065	0.2891
Pre-operative baseline sCreat value	-0.000	0.002	0.8001
Baseline eGFR: > 45 mL/min/1.73m2	-0.204	0.114	0.0745
Type of surgery: CABG with 3 or more distal anastomoses	-0.080	0.075	0.2867
CPB-pump time	-0.003	0.002	0.2060
Cross-clamp time	0.003	0.002	0.2046

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