

**Appendix 5 (as supplied by the authors): Characteristics of patients in the main SIRS trial (N = 7507), the kidney substudy (N = 7286), and the subsample of patients with serial postoperative serum creatinine assessments (N = 4824)<sup>a,b</sup>**

	<b>SIRS</b>	<b>Kidney substudy</b>	<b>p value<sup>c</sup></b>	<b>Subsample with serial creatinine assessment</b>	<b>p value<sup>d</sup></b>
	<b>(n = 7507)</b>	<b>(n = 7286)</b>		<b>(n = 4824)</b>	
Age, mean (SD), years	68 (14)	68 (14)	0.8	68 (14)	0.5
Women, No. (%)	2970 (39.6%)	2884 (39.6%)	0.98	1950 (40.4%)	0.8
Body mass index, mean (SD), kg/m <sup>2</sup>	27 (6)	27 (6)	0.7	27 (6)	0.2
<b>Ethnicity, No. (%)</b>					
African	70 / 7017 (1.0%)	60 / 6803 (0.9%)	0.8	44 (0.9%)	0.3
Asian, including South Asian	1833 / 7017 (26.1%)	1798 / 6803 (26.4%)		1285 (26.6%)	
Caucasian	4284 / 7017 (61.2%)	4167 / 6803 (61.3%)		2902 (60.2%)	
Aboriginal	12 / 7017 (0.2%)	10 / 6803 (0.2%)		5 (0.1%)	
Hispanic	495 / 7017 (7.1%)	468 / 6803 (6.9%)		356 (7.4%)	
Middle-Eastern	323 / 7017 (4.6%)	300 / 6803 (4.4%)		250 (5.2%)	
<b>Year of Randomization, No. (%)</b>					
2007-2010	600 (8.0%)	591 (8.1%)	0.97	0 (0%)	<0.001
2011	1499 (20.0%)	1444 (19.8%)		0 (0%)	
2012	2957 (39.4%)	2864 (39.3%)		2437 (50.5%)	
2013	2451 (32.7%)	2387 (32.8%)		2387 (49.5%)	

	<b>SIRS</b>	<b>Kidney substudy</b>	<i>p</i> value <sup>c</sup>	<b>Subsample with serial creatinine assessment</b>	<i>p</i> value <sup>d</sup>
	(n = 7507)	(n = 7286)		(n = 4824)	
<b>Location, No. (%)</b>					
North America	3324 (44.3%)	3220 (44.2%)	0.9	1798 (37.3%)	<0.001
South America	595 (7.9%)	564 (7.7%)		445 (9.2%)	
Europe	1046 (13.9%)	1022 (14.0%)		823 (17.1%)	
Asia	1788 (23.8%)	1760 (24.2%)		1238 (25.7%)	
Australia	453 (6.0%)	442 (6.1%)		284 (5.9%)	
Middle East	301 (4.0%)	278 (3.8%)		236 (4.9%)	
<b>Past Medical History, No. (%)</b>					
Congestive heart failure	2026 (27.0%)	1963 (26.9%)	0.9	1319 (27.3%)	0.6
Atrial fibrillation	1709 (22.8%)	1664 (22.8%)	0.9	1090 (22.6%)	0.8
Previous cardiac surgery	1157 (15.4%)	1129 (15.5%)	0.8	707 (14.7%)	0.2
CABG	396 (5.3%)	383 (5.3%)	0.9	220 (4.6%)	0.03
Valvular	669 (8.9%)	653 (9.0%)	0.9	425 (8.8%)	0.8
Other	233 (3.1%)	228 (3.1%)	0.9	143 (3.0%)	0.6
Stroke	622 (8.3%)	593 (8.1%)	0.6	373 (7.7%)	0.2
Diabetes	1975 (26.3%)	1871 (25.7%)	0.2	1261 (26.1%)	0.8
Hypertension	4967 (66.2%)	4793 (65.8%)	0.5	3230 (67.0%)	0.2

	<b>SIRS</b>	<b>Kidney substudy</b>	<b>p value<sup>c</sup></b>	<b>Subsample with serial creatinine assessment</b>	<b>p value<sup>d</sup></b>
	<b>(n = 7507)</b>	<b>(n = 7286)</b>		<b>(n = 4824)</b>	
Peripheral artery disease	782 (10.4%)	744 (10.2%)	0.6	489 (10.1%)	0.5
Smoking (within 12 months)	947 (12.6%)	919 (12.6%)	0.99	609 (12.6%)	0.98
<b>Left Ventricular Ejection Fraction, No. (%)</b>					
≥ 50%	4716 / 7437 (63.4%)	4594 / 7218 (63.7%)	0.6	2993 / 4766 (62.8%)	0.4
< 50%	2721 / 7437 (36.6%)	2624 / 7218 (36.4%)		1773 / 4766 (37.2%)	
<b>Estimated glomerular filtration rate</b>					
eGFR, mean (SD), mL/min per 1.73 m <sup>2</sup>	72 (23)	73 (22)	<0.001	73 (22)	<0.001
<b>eGFR category</b>					
<b>&gt; 60 mL/min per 1.73 m<sup>2</sup></b>					
No. (%)	5214 / 7489 (69.6%)	5152 (70.7%)	0.04	3440 (71.3%)	0.01
Mean (SD), mL/min per 1.73m <sup>2</sup>	83 (17)	83 (17)		84 (17)	
<b>≤ 60 mL/min per 1.73 m<sup>2</sup></b>					
No. (%)	2275 / 7489 (30.4%)	2134 (29.3%)		1384 (28.7%)	
Mean (SD), mL/min per 1.73m <sup>2</sup>	45 (12)	47 (10)		47 (10)	
≤ 45 mL/min per 1.73 m <sup>2</sup>	909 / 7489 (12.1%)	788 (10.8%)	<0.001	505 (10.5%)	<0.001
≤ 30 mL/min per 1.73 m <sup>2</sup>	268 / 7489 (3.6%)	161 (2.2%)	<0.001	115 (2.4%)	<0.001

	SIRS (n = 7507)	Kidney substudy (n = 7286)	p value <sup>c</sup>	Subsample with serial creatinine assessment (n = 4824)	p value <sup>d</sup>
<b>Pre-randomization medication use, No. (%)</b>					
ACE inhibitor or angiotensin receptor blocker	4112 (54.8%)	3999 (54.9%)	0.9	2715 (56.3%)	0.04
ACE inhibitor	2715 / 7017 (38.7%)	2645 / 6803 (38.9%)	0.8	1919 (39.8%)	0.1
Angiotensin receptor blocker	1233 / 7017 (17.6%)	1187 / 6803 (17.5%)	0.8	874 (18.1%)	0.3
Statin <sup>b</sup>	4223 (56.3%)	4076 (55.9%)	0.6	2705 (56.1%)	0.8
Diuretic	4148 (55.3%)	4023 (55.2%)	0.9	2719 (56.4%)	0.1
Aspirin	3426 (45.6%)	3304 (45.4%)	0.6	2074 (43.0%)	<.001
<b>Surgery, No. (%)</b>					
Evidence of non-elective surgery <sup>e</sup>	1446 (19.3%)	1404 (19.3%)	0.98	957 (19.8%)	0.3
Preoperative use of inotropes or vasopressors	618 (8.2%)	608 (8.3%)	0.7	412 (8.5%)	0.4
Preoperative use of IABP or VAD	127 (1.7%)	122 (1.7%)	0.9	92 (1.9%)	0.2
Previous MI within 30 days of surgery	864 (11.5%)	834 (11.5%)	0.9	578 (12.0%)	0.3
<b>Surgery Type, No. (%)</b>					
Isolated CABG	1587 (21.1%)	1534 (21.1%)	0.7	985 (20.4%)	0.09
Isolated valve	2437 (32.5%)	2411 (33.1%)		1670 (34.6%)	
CABG and valve	1827 (24.3%)	1791 (24.6%)		1156 (24.0%)	
Other <sup>f</sup>	1656 (22.1%)	1550 (21.3%)		1013 (21.0%)	

*Abbreviations:* ACE, angiotensin converting enzyme; CABG, coronary artery bypass graft; eGFR, estimated glomerular filtration rate; IABP, intra-aortic balloon pump; MI, myocardial infarction; SIRS, Steroids in Cardiac Surgery; VAD, ventricular assist device.

<sup>a</sup> All baseline characteristics (except surgical data) were assessed before randomization; surgical data (i.e. preoperative use of inotropes or vasopressors, or IABP or VAD, and surgery type) were assessed at the time of surgery. The median time from randomization to surgery was 17 hours (interquartile range, 3-26). Time of surgery was missing for 95 SIRS study patients. Time of randomization was missing for all 490 patients in the pilot study.

<sup>b</sup> The SIRS trial contained 490 pilot patients, 483 of whom were included in the SIRS kidney substudy. All pilot patients (methylprednisolone [n=243] and placebo [240]) were missing data on pre-randomization body mass index, ethnicity, and pre-randomization use of ACE inhibitors or angiotensin receptor blockers (however, information on combined ACE/ARB use was available). Data on left ventricular ejection fraction was missing in 0.9% of patients. Missing data on the remaining variables was less than 0.2%. For missing data on categorical variables, the condition/medication/procedure was considered absent; for calculating eGFR, patients missing ethnicity were assumed to be white. Pilot patients who answered 'yes' to taking a statin or a non-statin lipid lowering agent were assumed to be taking a statin.

<sup>c</sup> Chi square tests or one-sample t tests were used to test whether the proportions or means were equal between patients in the SIRS trial and the kidney substudy.

<sup>d</sup> Chi square tests or one-sample t tests were used to test whether the proportions or means were equal between patients in the SIRS trial and the serial creatinine subsample.

<sup>e</sup> Evidence of non-elective surgery was defined by preoperative use of inotropes, vasopressors, an intra-aortic balloon pump, or a ventricular assist device, or history of a myocardial infarction in the 30 days before surgery.

<sup>f</sup> Surgery type 'other' includes patients who had an aorta surgery (patch enlargement, Bentall procedure, ascending aortic replacement, arch replacement, and/or descending thoracic aortic replacement) or cardiac ablation surgery, or some type of "other cardiac procedure." Patients in this category may have had one of CABG or valve surgery, but not both; if a patient had both CABG and valve as well as aorta surgery and/or cardiac ablation surgery, then they are included in the 'CABG and valve' category.