Supplemental Material

One-Year Outcomes of Rosuvastatin vs. Placebo in Sepsis-Associated Acute Respiratory Distress Syndrome: Prospective Follow-up of SAILS Randomized Trial

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Supplemental Figure 1. Enrollment and Follow-up – Performance-Based Physical Assessment

Enrolled in SAILS Trial
232 patients

Randomized to Rosuvastatin
124 patients

27 (22%) Died before hospital discharge
9 (7%) Died post-discharge & before follow-up
12 (10%) Not followed, study site closed
40 (32%) Exclusion criteria for follow-up study
17 (14%) Baseline cognitive impairment
16 (13%) Declined participation
4 (3%) Non-English speaker
3 (2%) Homeless

Consented & Eligible for ALTOS Follow-up
36 patients

6 Month Follow-up
Done 28 (78%)
Missed 8 (22%)
0 Ineligible – not IRB approved yet
1 (3%) Died

12 Month Follow-up
Done 25 (71%)
Missed 10 (29%)
0 Not followed, study site closed

Randomized to Placebo
108 patients

19 (18%) Died before hospital discharge
8 (7%) Died post-discharge & before follow-up
14 (13%) Not followed, study site closed
19 (18%) Exclusion criteria for follow-up study
9 (8%) Baseline cognitive impairment
5 (5%) Declined participation
1 (<1%) Non-English speaker
3 (3%) Homeless
1 (<1%) Other

Consented & Eligible for ALTOS Follow-up
48 patients

6 Month Follow-up
Done 39 (83%)
Missed 8 (17%)
1 Ineligible – not IRB approved yet

12 Month Follow-up
Done 30 (68%)
Missed 14 (32%)
2 Not followed, study site closed
2 (4%) Died

*Physical performance assessments were completed in patients from 12 hospitals (5 centers) of the 35 hospitals (11 centers) that participated in this study.*
### Supplemental Table 1. Post-Randomization ICU and Post-ICU Data, by Randomized Treatment Group

<table>
<thead>
<tr>
<th></th>
<th>Rosuva-</th>
<th>Placebo</th>
<th>Rosuva-</th>
<th>Placebo</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>statin</td>
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<td>statin</td>
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<tr>
<td></td>
<td>(n= 128)</td>
<td>(n= 144)</td>
<td>(n= 36)</td>
<td>(n= 48)</td>
</tr>
<tr>
<td><strong>ICU data</strong></td>
<td></td>
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<tr>
<td>Daily morning glucose (mmol/L)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>127 (22)</td>
<td>121 (22)</td>
<td>132 (30)</td>
<td>117 (11)</td>
</tr>
<tr>
<td>Daily minimum glucose (mmol/L)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>115 (22)</td>
<td>108 (24)</td>
<td>124 (29)</td>
<td>110 (11)</td>
</tr>
<tr>
<td>Any corticosteroids, n (%)</td>
<td>43 (34)</td>
<td>49 (34)</td>
<td>7 (19)</td>
<td>15 (31)</td>
</tr>
<tr>
<td>If any steroids, number of days&lt;sup&gt;c&lt;/sup&gt;</td>
<td>6 (1)</td>
<td>6 (1)</td>
<td>6 (1)</td>
<td>6 (1)</td>
</tr>
<tr>
<td>Neuromuscular abnormality&lt;sup&gt;d&lt;/sup&gt;</td>
<td>11 (9)</td>
<td>13 (9)</td>
<td>5 (14)</td>
<td>5 (10)</td>
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<tr>
<td><strong>Post-discharge data</strong></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Statin use, n (%)</td>
<td>18 (23)</td>
<td>20 (22)</td>
<td>7 (26)</td>
<td>8 (24)</td>
</tr>
<tr>
<td>In-patient rehabilitation, n (%)</td>
<td>24 (21)</td>
<td>33 (26)</td>
<td>6 (17)</td>
<td>15 (32)</td>
</tr>
<tr>
<td>Any out-patient physical and/or occupational therapy, n (%)</td>
<td>54 (47)</td>
<td>61 (48)</td>
<td>16 (46)</td>
<td>23 (49)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Mean (SD) values are presented unless otherwise indicated. No statistically significant differences between Rosuvastatin and placebo. Number of unknown or missing data for patient reported outcomes and performance-based physical outcomes, respectively: Any steroids= 0, 0; neuromuscular abnormality= 5, 0; statin use= 101, 24; in-patient rehabilitation= 32, 2; out-patient therapy= 32, 2

<sup>b</sup>Only available for those co-enrolled in the EDEN trial: Patient reported outcomes (n=48) and performance-based physical outcomes (n=15)

<sup>c</sup>Ascertainment from day 0 to day 7 or until unassisted breathing, whichever came first

<sup>d</sup>Includes diagnosis or mention of myopathy, myositis, neuropathy, muscle weakness, paralysis based on medical records review.