

**N patients  
screened = 974**

**N not approached/met exclusion criteria = 210**

**N patients eligible  
= 764**

**Consent not obtained N = 554**  
• Declined consent  
• High CPAP/NIPPV before consent finalized  
• Other reason(s)

**N patients enrolled  
(i.e. consented) = 210**

**N treated with OPEN label High CPAP/NIPPV without randomization = 18**  
**N did not require randomization = 92**

**N randomized to  
High CPAP = 48**

**N randomized to  
NIPPV = 52**

**N with crossover to NIPPV  
within 1<sup>st</sup> 7 days = 11**

**N with crossover to High CPAP  
within 1<sup>st</sup> 7 days = 4**

**N NRS failure ≤7 days = 30**  
• N cross-overs = 10  
• N intubation = 13  
• N exceeded max pressures = 6  
• N changed to alternate mode = 1

**N NRS failure ≤7 days = 28**  
• N cross overs = 2  
• N intubation = 17  
• N exceeded max pressures = 9  
• N changed to alternate mode = 0