

Table 10: ANCOVA Model on the Change in Borg Scale From the End of Methacholine Challenge Test to 1, 3, 5, 10, 20 and 30 Minutes After Study Drug Intake (ITT Population)

Change in Borg Scale	CHF1535 100/6 µg NEXThaler® (Test) N=63	CHF1535 100/6 µg pMDI (Reference) N=62	Placebo N=63
1 minute			
Adjusted mean (95% CI)	-0.788 (-1.015;-0.561)	-1.146 (-1.376;-0.915)	-0.597 (-0.824;-0.369)
Test vs Reference			
Adj. mean difference (95% CI)	0.358 (0.034;0.681)	- -	- -
p-value	0.031	-	-
Active treatments vs placebo			
Adj. mean difference (95% CI)	-0.191 (-0.513;0.131)	-0.549 (-0.870;-0.227)	- -
p-value	0.242	<0.001	-
3 minutes			
Adjusted mean (95% CI)	-1.675 (-1.923;-1.427)	-1.708 (-1.960;-1.456)	-1.170 (-1.419;-0.921)
Test vs Reference			
Adj. mean difference (95% CI)	0.033 (-0.322;0.387)	- -	- -
p-value	0.856	-	-
Active treatments vs placebo			
Adj. mean difference (95% CI)	-0.505 (-0.857;-0.153)	-0.538 (-0.889;-0.186)	- -
p-value	0.005	0.003	-
5 minutes			
Adjusted mean (95% CI)	-2.144 (-2.381;-1.907)	-2.166 (-2.407;-1.926)	-1.545 (-1.783;-1.307)
Test vs Reference			
Adj. mean difference (95% CI)	0.022 (-0.316;0.360)	- -	- -
p-value	0.897	-	-

Active treatments vs placebo			
Adj. mean difference (95% CI) p-value	-0.599 (-0.935;-0.263) <0.001	-0.621 (-0.957;-0.286) <0.001	- - -
10 minutes			
Adjusted mean (95% CI)	-2.784 (-3.006;-2.562)	-2.785 (-3.010;-2.559)	-2.035 (-2.258;-1.812)
Test vs Reference			
Adj. mean difference (95% CI) p-value	0.001 (-0.317;0.318) 0.997	- - -	- - -
Active treatments vs placebo			
Adj. mean difference (95% CI) p-value	-0.750 (-1.065;-0.434) <0.001	-0.750 (-1.065;-0.435) <0.001	- - -
20 minutes			
Adjusted mean (95% CI)	-3.381 (-3.576;-3.185)	-3.254 (-3.453;-3.055)	-2.769 (-2.965;-2.573)
Test vs Reference			
Adj. mean difference (95% CI) p-value	-0.127 (-0.406;0.153) 0.371	- - -	- - -
Active treatments vs placebo			
Adj. mean difference (95% CI) p-value	-0.612 (-0.889;-0.334) <0.001	-0.485 (-0.762;-0.208) <0.001	- - -
30 minutes			
Adjusted mean (95% CI)	-3.684 (-3.873;-3.495)	-3.511 (-3.703;-3.319)	-3.279 (-3.468;-3.089)
Test vs Reference			
Adj. mean difference (95% CI) p-value	-0.173 (-0.443;0.097) 0.208	- - -	- - -
Active treatments vs placebo			
Adj. mean difference (95% CI) p-value	-0.405 (-0.674;-0.137) 0.003	-0.233 (-0.501;0.036) 0.089	- - -

N = number of subjects in the population

Source: [Table 14.2.1.19](#)