

Supplementary data

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TABLE S1 Reported concomitant medications during the 12-week treatment period

Concomitant medication, n (%)	Tiotropium Respimat® 5 µg once daily (n=130)	Tiotropium Respimat® 2.5 µg once daily (n=127)	Placebo Respimat® once daily (n=135)	Total (N=392)
Glucocorticosteroids	130 (100)	127 (100)	135 (100)	392 (100)
Inhaled	130 (100)	127 (100)	135 (100)	392 (100)
Intravenous/intramuscular	1 (0.8)	0	0	1 (0.3)
Oral	3 (2.3)	1 (0.8)	2 (1.5)	6 (1.5)
Intranasal	25 (19.2)	31 (24.4)	34 (25.2)	90 (23.0)
Other	2 (1.5)	2 (1.6)	4 (3.0)	8 (2.0)
Use of anticholinergics	1 (0.8)	0	0	1 (0.3)
Long-acting	0	0	0	0
Short-acting	1 (0.8)	0	0	1 (0.3)
β ₂ -agonists	108 (83.1)	102 (80.3)	116 (85.9)	326 (83.2)
Long-acting	107 (82.3)	101 (79.5)	116 (85.9)	324 (82.7)
Short-acting	4 (3.1)	3 (2.4)	0	7 (1.8)
Theophyllines	8 (6.2)	6 (4.7)	7 (5.2)	21 (5.4)
Leukotriene modifiers	102 (78.5)	104 (81.9)	109 (80.7)	315 (80.4)

Treated set.

TABLE S2 *Post hoc* analysis of peak FEV_{1(0-3h)} response at Week 12 by age group

Treatment	Adjusted mean response ± SE	Active versus placebo Respimat®		
		Adjusted mean of difference ± SE	95% CI	p value
12–14 years				
Tiotropium Respimat® 5 µg once daily (n=71)	523 ± 46	95 ± 65	–33–223	0.146
Tiotropium Respimat® 2.5 µg once daily (n=65)	606 ± 48	179 ± 66	48–309	0.007
Placebo Respimat® once daily (n=72)	427 ± 46			
15–17 years				
Tiotropium Respimat® 5 µg once daily (n=59)	695 ± 67	106 ± 94	–79–292	0.261
Tiotropium Respimat® 2.5 µg once daily (n=61)	628 ± 66	39 ± 94	–146–224	0.678
Placebo Respimat® once daily (n=60)	589 ± 66			

Full analysis set. Adjusted for treatment, visit, baseline, treatment-by-visit interaction and baseline-by-visit interaction. Subgroup baseline mean FEV₁, mL:

2301 for 12–14 years; 2785 for 15–17 years. Treatment-by-subgroup interaction p value = 0.656.

CI: confidence interval; FEV₁: forced expiratory volume in 1 s; peak FEV_{1(0-3h)}: peak forced expiratory volume in 1 s within 3 h post-dosing; SE: standard error.

TABLE S3 *Post hoc* analysis of trough FEV₁ response at Week 12 by age group

Treatment	Adjusted mean response ± SE	Active versus placebo Respimat®			
		Adjusted mean of difference ± SE	95% CI	p value	
12–14 years					
Tiotropium Respimat® 5 µg once daily (n=71)	302 ± 50	57 ± 70	–80–195	0.413	
Tiotropium Respimat® 2.5 µg once daily (n=65)	414 ± 52	169 ± 71	29–309	0.018	
Placebo Respimat® once daily (n=72)	244 ± 49				
15–17 years					
Tiotropium Respimat® 5 µg once daily (n=59)	438 ± 71	67 ± 100	–129–264	0.501	
Tiotropium Respimat® 2.5 µg once daily (n=61)	426 ± 70	55 ± 99	–140–251	0.576	
Placebo Respimat® once daily (n=60)	370 ± 70				

Full analysis set. Adjusted for treatment, visit, baseline, treatment-by-visit interaction and baseline-by-visit interaction. Subgroup baseline mean FEV₁, mL:

2301 for 12–14 years; 2785 for 15–17 years. Treatment-by-subgroup interaction p value = 0.484.

CI: confidence interval; FEV₁: forced expiratory volume in 1 s; SE: standard error.

TABLE S4 Change from baseline in weekly mean rescue medication use at Week 12: weekly mean number of puffs of rescue medication during the daytime, night-time and full 24-hour period

Treatment and parameter	Adjusted mean response \pm SE	Active versus placebo Respimat [®]		
		Adjusted mean of difference \pm SE, mL	95% CI	p value
Daytime, number of puffs				
Tiotropium Respimat [®] 5 μ g once daily (n=130)	-0.312 \pm 0.073	-0.049 \pm 0.093	-0.232–0.133	0.595
Tiotropium Respimat [®] 2.5 μ g once daily (n=124)	-0.295 \pm 0.075	-0.032 \pm 0.094	-0.217–0.153	0.731
Placebo Respimat [®] once daily (n=131)	-0.262 \pm 0.073			
Night-time, number of puffs				
Tiotropium Respimat [®] 5 μ g once daily (n=129)	-0.159 \pm 0.065	0.021 \pm 0.082	-0.140–0.182	0.795
Tiotropium Respimat [®] 2.5 μ g once daily (n=124)	-0.092 \pm 0.066	0.089 \pm 0.083	-0.074–0.252	0.284
Placebo Respimat [®] once daily (n=131)	-0.180 \pm 0.064			
24-hour period, number of puffs				

Tiotropium Respimat [®] 5 µg once daily (n=130)	-0.540 ± 0.120	-0.058 ± 0.151	-0.355-0.239	0.703
Tiotropium Respimat [®] 2.5 µg once daily (n=124)	-0.483 ± 0.122	-0.001 ± 0.153	-0.301-0.300	0.996
Placebo Respimat [®] once daily (n=131)	-0.482 ± 0.118			

Full analysis set. Adjusted for treatment, week, baseline, treatment-by-week interaction and baseline-by-week interaction. Common baseline mean ± standard deviation: daytime = 0.972 ± 1.100; night-time = 0.749 ± 0.934; 24-hour period = 1.649 ± 1.906.

CI: confidence interval; SE: standard error.