

Appendix Table F54. Clinical outcomes after tolterodine vs. placebo (results from randomized controlled clinical trials pooled with random effects models)

Drug	Outcome	Publications	Patients	Rate active/control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)
Tolterodine	Continence	4 ^{56,318,365,473}	3,404	53.2/43.7	1.2 (1.1 to 1.4)	0.09 (0.04 to 0.13)	12 (8 to 25)
Tolterodine	Improvement in UI	7 ^{56,286,301,318,323,364,370,470}	6,119	45/37	1.3 (1.1 to 1.4)	0.10(0.04 to 0.15)	10 (7 to 24)
Tolterodine	Treatment failure	6 ^{56, 286, 301, 323, 364, 365, 470}	4,260	9/16	0.7 (0.5 to 1.0)	-0.04 (-0.09 to 0.00)	
Tolterodine	Adverse effects	12 ^{56, 219, 253, 260, 279, 312, 314, 316, 325, 345, 360, 365}	4,162	44.7/38.1	1.2 (1.1 to 1.3)	0.08 (0.05 to 0.11)	13 (9 to 21)
Tolterodine	Serious adverse effects	5 ^{56, 279, 331, 346, 349}	3,550	1.8/3.1	0.6 (0.4 to 0.9)	-0.01 (-0.02 to 0.00)	
Tolterodine	Discontinuation	9 ^{52, 56, 253, 260, 279, 280, 323, 331, 363, 470}	5,384	5.8[6.4]	0.9 (0.8 to 1.2)	-0.01 (-0.01 to 0.00)	
Tolterodine	Discontinuation Adverse effects	10 ^{52, 56, 219, 253, 279, 280, 301, 312, 318, 325, 346, 360, 470}	4,466	4/3	1.0 (0.6 to 1.7)	0.01 (-0.01 to 0.02)	
Tolterodine	Discontinuation Treatment failure	5 ^{52, 56, 301, 325, 470}	4,049	0.7/1.6	0.5 (0.2 to 0.9)	-0.01 (-0.02 to 0.00)	
Tolterodine	Autonomic nervous system disorders	3 ^{279, 314, 349}	831	27.2/15.5	1.8 (1.3 to 2.4)	0.11 (0.03 to 0.19)	9 (5 to 31)
Tolterodine	Blurred vision	2 ^{52, 260}	608	1.3/3.0	0.5 (0.2 to 1.5)	-0.01 (-0.04 to 0.01)	
Tolterodine	Constipation	14 ^{52, 56, 253, 260, 280, 301, 312, 314, 318, 325, 331, 346, 360, 365, 381, 470}	9,592	4/3	1.4 (1.1 to 1.8)	0.01 (0.00 to 0.02)	100 (63 to 333)
Tolterodine	Diarrhea	4 ^{56, 325, 331, 346, 381, 470}	4,056	2/2	1.3 (0.8 to 2.0)	0.01 (0.00 to 0.01)	
Tolterodine	Dizziness	6 ^{56, 253, 301, 325, 331, 346, 381}	5,257	2/2	1.1 (0.7 to 1.7)	0.00 (0.00 to 0.01)	
Tolterodine	Dry mouth	14 ^{52, 56, 219, 253, 260, 301, 312, 316, 318, 331, 345, 360, 365, 470}	7,637	18.4/6.7	2.6 (2.2 to 3.2)	0.13 (0.10 to 0.15)	8 (6 to 10)
Tolterodine	Dyspepsia	6 ^{56, 219, 325, 331, 345, 346, 381}	3,525	3/2	1.8 (0.9 to 3.5)	0.02 (0.001 to 0.03)	67 (34 to 1000)
Tolterodine	Fatigue	4 ^{56, 253, 301, 331}	3,234	1.9/0.7	2.5 (1.2 to 5.2)	0.01 (0.00 to 0.02)	83 (45 to 500)
Tolterodine	General body disorders	2 ^{279, 314}	308	22.3/18.6	1.2 (0.7 to 2.1)	0.02 (-0.10 to 0.15)	
Tolterodine	Headache	11 ^{56, 253, 260, 280, 301, 312, 314, 325, 331, 345, 346, 365, 381, 470}	6,766	4/4	1.2 (1.0 to 1.6)	0.01 (0.00 to 0.02)	91 (1 to 500)

Appendix Table F54. Clinical outcomes after tolterodine vs. placebo (results from randomized controlled clinical trials pooled with random effects models) (continued)

Drug	Outcome	Publications	Patients	Rate active/control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)
Tolterodine	Insomnia	2 ^{331, 365, 381}	1,428	1.7/1.3	2.1 (0.2 to 26.6)	0.01 (-0.02 to 0.04)	
Tolterodine	Nasopharyngitis	5 ^{56, 253, 254, 301, 365, 370}	2,835	3/3	1.2 (0.8 to 1.8)	0.01 (-0.01 to 0.02)	
Tolterodine	Nausea	7 ^{56, 219, 253, 325, 331, 346, 381}	5,642	1.6/2.0	0.8 (0.5 to 1.1)	0.00 (-0.01 to 0.01)	
Tolterodine	Somnolence	2 ^{325, 331, 381}	1,869	1/1	0.9 (0.2 to 4.6)	0.00 (-0.01 to 0.02)	
Tolterodine	Urinary tract infection	5 ^{56, 314, 325, 331, 365, 381, 470}	4,465	2/3	1.0 (0.6 to 1.6)	0.00 (-0.01 to 0.01)	
Tolterodine	Abdominal pain	5 ^{56, 312, 325, 331, 346, 381}	4,637	3/2	1.6 (1.0 to 2.4)	0.01 (0.00 to 0.02)	
Tolterodine	Abnormal vision	2 ^{331, 360, 381}	1,141	2/1	1.3 (0.5 to 3.6)	0.00 (-0.01 to 0.01)	

Appendix Table F55. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence)

Studies, reference	Dose, mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat 95% CI)	Attributable events (95% CI)
≥7 consecutive dry days							
Chapple, 2005 ²⁵⁶	7.5	19/337	15/388	1.46 (0.75; 2.82)	0.018 (-0.013; 0.049)		
Chapple, 2005 ²⁵⁶	15	24/334	16/388	1.74 (0.94; 3.22)	0.031 (-0.003; 0.065)		
≥3 dry days/week							
Chapple, 2005 ²⁵⁶	7.5	55/337	43/388	1.47 (1.02; 2.13)	0.052 (0.002; 0.103)	19 (10; 486)	52 (2; 103)
Chapple, 2005 ²⁵⁶	15	61/334	48/388	1.48 (1.04; 2.09)	0.059 (0.006; 0.112)	17 (9; 164)	59 (6; 112)
Reduction in incontinence episodes: ≥50%							
Chapple, 2005 ²⁵⁶	7.5	222/337	202/388	1.27 (1.12; 1.43)	0.138 (0.067; 0.209)	7 (5; 15)	138 (67; 209)
Chapple, 2005 ²⁵⁶	15	234/334	217/388	1.25 (1.12; 1.40)	0.141 (0.072; 0.211)	7 (5; 14)	141 (72; 211)
Reduction in incontinence episodes: ≥70%							
Chapple, 2005 ²⁵⁶	7.5	162/337	128/388	1.46 (1.22; 1.74)	0.151 (0.080; 0.222)	7 (5; 13)	151 (80; 222)
Chapple, 2005 ²⁵⁶	15	190/334	151/388	1.46 (1.25; 1.71)	0.180 (0.108; 0.252)	6 (4; 9)	180 (108; 252)
Reduction in incontinence episodes: ≥90%							
Chapple, 2005 ²⁵⁶	7.5	91/337	66/388	1.59 (1.20; 2.10)	0.100 (0.040; 0.160)	10 (6; 25)	100 (40; 160)
Chapple, 2005 ²⁵⁶	15	94/334	66/388	1.65 (1.25; 2.19)	0.111 (0.050; 0.172)	9 (6; 20)	111 (50; 172)
Incontinence impact							
Abrams, 2008 ⁴⁷	7.5	52/337	30/388	2.00 (1.30; 3.05)	0.077 (0.030; 0.124)	13 (8; 33)	77 (30; 124)
Abrams, 2008 ⁴⁷	15	46/334	30/388	1.78 (1.15; 2.75)	0.060 (0.015; 0.106)	17 (9; 67)	60 (15; 106)
Severity measures							
Abrams, 2008 ⁴⁷	7.5	47/337	27/388	2.00 (1.28; 3.14)	0.070 (0.025; 0.115)	14 (9; 40)	70 (25; 115)
Abrams, 2008 ⁴⁷	15	46/334	27/388	1.98 (1.26; 3.11)	0.068 (0.023; 0.113)	15 (9; 43)	68 (23; 113)
Role limitations							
Abrams, 2008 ⁴⁷	7.5	65/337	46/388	1.63 (1.15; 2.30)	0.074 (0.021; 0.127)	13 (8; 47)	74 (21; 127)
Abrams, 2008 ⁴⁷	15	59/334	46/388	1.49 (1.04; 2.13)	0.058 (0.006; 0.110)	17 (9; 165)	58 (6; 110)
Social limitations							
Abrams, 2008 ⁴⁷	7.5	57/337	42/388	1.56 (1.08; 2.26)	0.061 (0.010; 0.111)	16 (9; 97)	61 (10; 111)
Abrams, 2008 ⁴⁷	15	54/334	42/388	1.49 (1.03; 2.17)	0.053 (0.003; 0.104)	19 (10; 305)	53 (3; 104)
Physical limitations							
Abrams, 2008 ⁴⁷	7.5	58/337	49/388	1.36 (0.96; 1.94)	0.046 (-0.006; 0.098)		
Abrams, 2008 ⁴⁷	15	53/334	49/388	1.26 (0.88; 1.80)	0.032 (-0.019; 0.084)		
Emotions							
Abrams, 2008 ⁴⁷	7.5	56/337	44/388	1.47 (1.02; 2.11)	0.053 (0.002; 0.104)	19 (10; 493)	53 (2; 104)
Abrams, 2008 ⁴⁷	15	53/334	44/388	1.40 (0.96; 2.03)	0.045 (-0.005; 0.096)		
Personal relationships							
Abrams, 2008 ⁴⁷	7.5	24/337	20/388	1.38 (0.78; 2.46)	0.020 (-0.016; 0.055)		
Abrams, 2008 ⁴⁷	15	23/334	20/388	1.34 (0.75; 2.39)	0.017 (-0.018; 0.052)		