Additional file 4: Baseline characteristics of men in the included studies

Author	Finasteride Daily dose (mg)	Control	Duration	Baseline entry criteria	Patients	Score used	Symptom score	Qmax (mL/s)	Mean flow rate (mL/s)	Prostate volume (cm^3)	Residual urine (ml)	Total voided volume (ml)	PSA (ng/ml)	DHT	Bother	Sexual function score (0-20)
Abrams et al, 1999	5 mg (n=81) At 9 & 12 mth n=69	Placebo (n=40) At 9 mth n=37	12 months	Enlarged prostate by DRE Lower urinary tract symptoms Objective evidence of outlet obstruction (pressure flow) Mean symptom score shows moderate / severe at baseline PSA ≤10 ng/ml	Mean age: 67 years	AUA	Fin: 19.4 ± 6.3 Placebo: 17.4 ± 6.8 % obstructed: Fin: 76% Placebo: 82.5%	Fin: 7.6 ± 2.4 Placebo: 7.1 ±2.0	Fin: 10.0 ± 4.2 Placebo: 9.1 ± 3.7	Fin: 45.1 Placebo: 44.8;			<10 ng/ml			
Andersen et al, 1995	5 mg (n=353) Completed (287)	Placebo (n=354) Completed (290)	24 months	Moderate Enlarged prostate by DRE Age ≤80 Max urinary flow rate ≥5 & ≤15 cc/s at screening.	707 patients enrolled Mean age 65.5 yrs (range 46-80)	Boyarsky (modified Bolognese)	Fin: 13.4 Placebo: 13.1 Obstructive score: Fin: 8.8 Placebo: 8.6	Fin: 10.2 Placebo: 10.5	Fin: 5.2 Placebo: 5.5	Prostate volume: Fin: 40.6 Placebo: 41.7	Post-void residual volume <150 cc		<10 ng/ml			
Beisland HO et al, 1992	5 mg (n=94)	Placebo (n=88)	6 months	Enlarged prostate (palpation) Symptoms of urinary obstruction Max urinary flow <15 mL/s	Number patients enrolled: 182 Number patients completed: 168 45% of patients in each group had mild symptoms. Mean age 67 years (range 46-80)	Boyarsky (modified)	Fin: 8.8 ± 6.1 Placebo: 7.8 ± 4.9 Obstructive symptom score: Fin: 2.2 ± 4.0; Placebo: 1.1 ± 3.3 Troublesome symptom score: Fin: 7.1 ±3.7 Placebo: 6.8 ±3.9	Fin: 8.0 ±3.0; Placebo: 7.6 ±3.1		Median Fin: 44.2 ± 22.4 Placebo: 43.8 ± 24.1				Fin: 74.6 ng/dl Placebo: 65.2 ng/dl		
Byrnes et al, 1995	5 mg (n=1821)	Placebo (n=596)	12 months	Clinical diagnosis of BPH with prostate enlargement on DRE Moderate / severe (1.9% pts had mild symptoms with finasteride & 2.2% with placebo)	2917 patients enrolled. Efficacy population: 2342 Safety population: 2417 Aged ≥45 years Mainly Caucasian	AUA	Baseline not provided						<10 ng/ml	Fin: 48.2ng/dl Placebo: 46.6 ng/dl	BPH Impact index (BII): max score 13 Fin:5.1 Placebo: 5.0	
Carraro et al, 1996	5 mg (n=545)	Permixon (serenoa repens) (n=553)	26 weeks	AUA ≥6, Max urinary flow 4-15 mL/s Clinical BPH by DRE (prostate >25 ml) PSA <10 ng/ml	1098 randomised Completed trial: 951 (Fin 484, permixon 467) Mean age 64 years (range 49-88) Mean body mass index: 26 (range 17-38) Quality of life score (0-6): Fin: 3.6 ±1.3 Placebo: 3.7 ±1.2	AUA (0-35)	Fin: 15.7 ±5.7.2; 26 wks -6.2 Permixon: 15.7 ±5.8	Fin: 10.8 ±2.8 Permixon: Baseline 10.6 ±2.8	Fin: 5.4±2.1 Placebo: 5.5 ±2.3	Fin: 44.0 ±20.6 Permixon: 43.0 ±19.6	Fin: 52 ±44 ml Placebo: 52 ±44 ml	Fin: 247 ±111ml Placebo: 241 ±104 ml	PSA <10 ng/ml Fin: 3.3 ±3.4 Placebo: 3.2 ±3.3			Fin: 8.4 ±5.5 Placebo: 8.5 ±5.5

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Debruyne et al, 1998 ALFIN study	5 mg (n=344)	Alfuzosin 10 mg daily (n=358) Combination (n=349) No placebo	6 months	AUA score ≥7 Qmax between 5-15 mL/s LUTS associated with BPH No threshold for prostate volume PSA <10 ng/ml	Randomised: 1051 patients. Completed study: 918 Aged 50-75 years LUTS related to BPH. 46% aged over 65 years. 32% had concomitant treated hypertension. 9% mild, 78% moderate, 21% severe at baseline Duration fof symptoms: about 3.5 years	AUA	Fin: 15.5 ±5.2 Alf: 15.3 ±5.5 Combination: 15.6 ±5.7	Fin: 9.8 ±2.6 Alf: 9.7 ±2.8 Combination: 10.1 ±3.5		Fin: 40.9 ±23.5; Alf: 41.4 ±25.7 Combination: 41.1 ±22.6			<10 ng/ml			
Finasteride study group, 1993 International study	1 mg (n=249) 5 mg (n=246)	Placebo (n=255)	12 months	Symptoms or urinary obstruction Voided vol ≥150 ml only included in analysis Max urinary flow rate <15 mL/s Prostate volume ≥30 cm3	Baseline total symptom score: 18 ±6 (moderate) Mean age: 66 yrs (range 46-83) Mean prostate volume (cm^3): Fin 1 mg: 47.5 ±22.5 Fin 5 mg: 47.0 ± 20.8 Placebo: 46.3 ±23.4	Boyarsky	Fin 1 mg: 18.7 ±6.0 Fin 5 mg: 18.6 ±6.0 Placebo: 18.2 ±5.9 Obstructive score: Fin 1 mg: 11.5 ±3.8 Fin 5 mg: 11.2 ±3.8 Placebo: 11.1 ±3.7	Fin 1 mg: 8.8 ±3.7 Fin 5 mg: 9.2 ±4.0 Placebo: 8.6 ±3.4		Fin 1 mg: 47.5 ±22.5 Fin 5 mg: 47.0 ±20.8 Placebo: 46.3 ±23.4			Fin 1 mg: 5.5 ± 7.3 Fin 5 mg: 5.8 ±6.7 Placebo: 5.7 ± 7.2	Fin 1 mg: 478.7 ±168.3 ng/dl Fin 5 mg: 486.9 ±190.2 ng/dl Placebo: 475.4 ±156.7 ng/dl		
Gormley et al, 1992 North American Study	1 mg (n=298) 5 mg (n=297)	Placebo (n=300)	12 months	Enlarged prostate on DRE Symptoms of urinary obstruction max urinary flow rate ≤15 mL/s, voided volume ≥ 150 ml	Completed trial (12 mth): Fin 1 mg (270) Fin 5 mg (257) Placebo (263) Mean age: 64 years (range 40-83) Mainly Caucasian	Boyarsky (modified, 0-36)	Fin 1 mg: 10.6 ±5.7 Fin 5 mg: 10.2 ±5.5 Placebo: 9.8 ±5.3 Obstructive symptom score: Fin 1 mg: 7.4 ±3.8 Fin 5 mg: 7.0 ±3.6 Placebo: 6.7 ±3.5	Fin 1 mg: 10.6 ±5.7 Fin 5 mg: 10.2 ±5.5 Placebo: 9.8 ±5.3	Fin 1 mg: Fin 5 mg: Placebo: 5.6 ±	Fin 1 mg: 60.9 ±34.3 Fin 5 mg: 58.6 ±30.5 Placebo: 61.0 ±36.5	Fin 1 mg: 76 ±94 Fin 5 mg: 73 ±89 Placebo: 73 ±91	Fin 1 mg: 244 ±94 Fin 5 mg: 258 ±112 Placebo: 260 ±114	Fin 1 mg: 3.8 ±7.2 Fin 5 mg: 3.6 ±4.2 Placebo: 4.1 ±4.8	Fin 1 mg: 3.8 ±7.2 Fin 5 mg: 3.6 ±4.2 Placebo: 42±18		
Isotalo et al, 2001	5 mg (n=26)	Placebo (n=29)	18 mth	AUR related to BPH. Ability to void after catheterisation and stent implant. Prostate volume measured by TRUS. No further details.	55 patients enrolled. 19 completed the trial. Mean age 71 years (range 52-89)	AUA	No significant changes between or within groups. No further details.	Fin: 6.2 Placebo: 7.0		Fin: 62 Placebo: 70	Fin: 86 Placebo: 81		Fin: 8.5 Placebo: 7.9			
Kirby et al, 1992	5 mg (n=29) 10 mg (n=16)	Placebo (n=21)	3 mth	Mean Boyarsky symptom score ≥8. Confirmed obstruction. Prostate volume by TRUS.	Outflow obstruction due to BPH Mean age 64 years (range 48-87)	Boyarsky	Fin 5 mg: Baseline 19.3; 3 mth -4.0 Fin 10 mg: Baseline 16.9; 3 mth -2.3 Placebo: Baseline 18.8	Fin 5 mg: 7.2 Fin 10 mg: 9.3 Placebo: 11.1		Fin 5 mg: 49.7 fin 10 mg: 54.3 Placebo: 37.7	Fin 5 mg: 104.2 Fin 10 mg: 161.2 Placebo: 151.9	Fin 5 mg: 205.2 Fin 10 mg: 234.9 Placebo: 217.9	Fin 5 mg: 4.1 Fin 10 mg: 3.0 Placebo: 5.0	mmol/L: Fin 5 mg: 1.7 Fin 10 mg: 2.7 Placebo: 1.8		

Author	Finasteride Daily dose (mg)	Control	Duration	Baseline entry criteria	Patients	Score used	Symptom score	Qmax (mL/s)	Mean flow rate (mL/s)	Prostate volume (cm^3)	Residual urine (ml)	Total voided volume (ml)	PSA (ng/ml)	DHT	Bother	Sexual function score (0-20)
Lepor et al, 1996 VA cooperative study.	5 mg (n=310)	Placebo (n=305) Terazosin 10 mg (n=305) Combination (n=309)	12 months	Voiding volume ≥150 ml No threshold for prostate enlargement. Measured using TRUS	1229 patients enrolled. Mean age: 65 yrs Mean prostate volume (cm3): 37 Mean total AUA symptom score: 16 Peak urinary flow rate (mL/s):10.5 Completed 1 yr: Fin (243) Terazosin (256) Combination (254) Placebo (254)	AUA (0-35)	Fin: 16.2 ± 5.4 Terazosin: 16.2 ±5.5 Combination: 15.9 ±5.7 Placebo: 15.8 ± 5.5	Fin: 10.6 ±2.5 Terazosin: 10.5 ±2.6 Combination: 10.4 ±2.7 Placebo: 10.4 ±2.6		Fin: 36.2 ±1.0 Terazosin: 37.5 ±1.1 Combination: 37.2 ±1.1 Placebo: 38.4 ±1.3			Fin: 2.2 ±1.8 Terazosin: 2.2 ±1.9 Combination: 2.3 ±2.0 Placebo: 2.4 ±2.1			
Lukkarinen et al, 1999	5 mg (n=33)	Placebo (n=31)	24 months	Moderate to severe symptoms of BPH treated by balloon dilatation; 50% reduction in symptoms. Enlarged prostate on DRE &TRUS (volume >30 cc) PSA <10 ng/ml	Completed trial (24mth): Fin (27) Placebo (25) Mean age: 65 years (range 50-82)	Boyarsky (modified, FDA 1977)	Fin: 7.0 Placebo: 7.0	Fin: 13.7 ±6.1 Placebo: 13.3 ±6.0		Fin: 41.9 ±9.8 Placebo: 46.7±12.3			Median Fin: 2.4 (range 0.5 to 8.1) Placebo: 2.5 (range 0.5 to 8.6)			
Marbergher et al, 1998 PROWESS	5 mg (n=1450)	Placebo (n=1452)	24 months	Moderate symptoms (at least 2) Enlarged prostate on DRE PSA <10 ng/ml Residual urine <150 ml Max urinary flow rate of 5-15 mL/s	2902 randomised. Completed trial: Fin (1119; 77.9%) Placebo (1092; 75%) Mean age 63 years (range 50-75) Mean obstructive symptom score: Fin: 9.3 ± 4.6 Placebo: 9.1 ±4.5 Mean duration of BPH (yrs): Fin:3.19 ±3.22 Placebo: 3.21 ± 3.27	Boyarsky	Fin: 14.5 ± 7.3 Placebo: 14.3 ±7.2 Obstructive score: Fin: 9.3 ±4.6 Placebo: 9.1 ±4.5	Fin: 11.2 ±5.9 Placebo: 10.9 ±3.6		Fin: 38.7 ± 20.1 Placebo: 39.2 ± 20.2 Measured in 890 (F) + 906 (Pl)			<10 ng/ml			
Marks et al, 1997	5 mg (n=26)	Placebo (n=15)	6 months DB	Symptomatic BPH (chronic symptoms of bladder outlet obstruction) AUA ≥9 (moderate / severe) Prostate enlargement on rectal examination TRUS & MRI	Completed study: Fin (26) Placebo (13) Mean age: 64 years (range 52-78) Mainly Caucasian	AUA	Fin: 17.0 ±5 Placebo: 16.0 ±2	Fin: 13.0 ±7 Placebo: 12.0 ±5					Fin: 2.7 ±2.5 Placebo: 3.3 ±3.1	Fin: 39 ±21 Placebo: 39 ±19		
McConnell et al, 1998 PLESS	5 mg (n=1524)	Placebo (n=1516)	6 months DB	Moderate/severe symptoms Enlarged prostate on DRE or MRI PSA <10 ng/ml	3040 patients enrolled Completed 4 yrs: Fin (1000) Placebo (883) Mean age: 64 yrs 95% Caucasian	Quasi- AUA (0-34)	Fin: 15 ± 6 Placebo: 15 ±6	Fin: 11.0 ±4.0 Placebo: 11.0 ±4.0		Fin: 55 ±26 Placebo: 54 ±25 Measured in 312 men. 157 (F) + 155 (Pl)			Fin: 2.8 ±2.1 Placebo: 2.8 ±2.1			

Author	Finasteride Daily dose (mg)	Control	Duration	Baseline entry criteria	Patients	Score used	Symptom score	Qmax (mL/s)	Mean flow rate (mL/s)	Prostate volume (cm^3)	Residual urine (ml)	Total voided volume (ml)	PSA (ng/ml)	DHT	Bother	Sexual function score (0-20)
Nickel et al, 1996 PROSPECT	5 mg (n=310)	Placebo (n=303)	24 months	Moderate symptoms . Enlarged prostate by DRE, TRUS PSA <10 ng/ml Max urinary flow rate 5-15 mL/s Total voided volume >150 ml Residual urine ≤150 ml	613 patients. Mean age: 63 years (range 46-80) Completed trial: Fin (246) Placebo (226)	Boyarsky	Fin: 15.8 ±7.6 Placebo: 16.6 ±7.2 Obstruction symptom score: Fin: 10.2 ±4.8 Placebo: 10.7 ±4.5	Fin: 11.1 ±3.7 Placebo: 10.9 ±3.5	Fin: 11.1 ±3.7 Placebo: 10.9 ±3.5	Fin: 44.1 ±23.5 Placebo: 45.8 ±22.4	Residual urine ≤150 ml	Total voided volume >150 ml	Baseline not provided. Mean change from baseline at : Fin: 1 yr -50%; 2 yr -50% Placebo: 1 yr +5.5%; 2 yr +13.3%			
Sokeland & Albrecht, 1997	1 capsule (n=244)	2 capsules Pro 120/160 (Sabal + urtica extract) (n=245)	48 weeks	Qmax >15 mL/s, voided volume ≥150 ml	Number enrolled: 543	AUA	Fin: 11.8 ±6.6 Pro 160/120: 11.3 ±6.5	Fin: 12.7 ±4.5 Pro 160/120: 12.7 ±4.4								
[Stoner et al, 1992 a]	Study 1 (n=86): Fin 5 mg (n=10) 10 mg (n=15) 20 mg (n=16) 40 mg (n=14) 80 mg (n=11)	Study 1: Placebo: (n=14)	Study 1: 12 weeks on & 12 weeks off treatment	Enlarged prostate volume >30 cc by MRI & TRUS (range 28-168 cm^3) Significant lower urinary tract obstruction	Number enrolled: 86 Number completed: 78 Mean age 65 years (range 40-80)					Fin 5 mg: 71.6 ±39.2 Placebo: 79.7 ±37.0						
[Stoner et al, 1992 b]	Study 2 (n=104): Fin 0.2 mg (n=18) 0.5 mg (n=15) 1.0 mg (n=17) 5 mg (n=15) 40 mg (n=13)	Study 2: Placebo (n=25)	Study 2: 24 wks	Prostate volume >30 cc by MRI (range 26 to 279 cm^3) Significant lower urinary tract obstruction	Number enrolled: 104 Number completed: 93 Mean age 64 years (range 40-80)	Boyarsky	Fin 1/5mg: 18.4 (no SD Placebo: 16.5 (no SD)	Fin 1/5mg: 9.5 (no SD) Placebo: 9.2 (no SD)		Fin 1 mg: 86.3 ±64.5 Fin 5 mg: 66.6 ±40.4 Placebo: 63.5 ±30.6			Median Fin1 mg: 4.0 Fin 5 mg: 1.5 Placebo: 2.4			
Tammela & Kontturi, 1993	5 mg (n=19)	Placebo (n=17)	6 months	Moderate / severe BPH with bladder outlet obstruction. Enlarged prostate-volume by TRUS Max urinary flow rate <15 mL/s. Voiding volume ≥150 ml	Number patients enrolled: 36 Number patients completed: 36 Mean age 65 years (range 54-80)	Boyarsky (modified)	Fin: 10.4 Placebo: 9.8	Fin: 7.7 ±2.3 Placebo: 8.8 ±3.3	Fin: 4.2 ±2.3 Placebo: 4.7 ±2.1		Fin: 117 ±97 Placebo: 93 ±67		Fin: Baseline 5.4 ±6.4; 6 mth 2.9 ±3.0 Placebo: Baseline 4.0 ±2.7; 6 mth 4.3 ±3.1			
Tenover et al, 1997	5 mg (n=1589 per protocol) 1736 analysed for safety	Placebo (n=523 per protocol) 579 analysed for safety	12 months	Moderate to severe symptoms of clinically diagnosed BPH. Enlarged prostate on DRE PSA <10 ng/ml	Number patients enrolled: 2808; 2315 randomised Mean age 63 years (range 45-94) Mainly Caucasian	AUA (0-35)	Fin: 19.03 Placebo: 18.35								BII (0-13) Fin: 4.76 Placebo: 4.67	
Yu et al, 1995	5 mg (n=25)	Placebo (n=25)	6 months	Bothersome symptoms of BPH. Enlarged prostate on DRE & TRUS	Number patients enrolled: 50 Number patients completed: 46 Mean age: 65 years (range 50-82)	AUA (0-35)	Fin: 19.45 ±6.63 Placebo: 16.68 ±4.06	Fin: 11.19 ±2.47 Placebo: 11.44 ±4.76	Fin: 5.52 ±2.0 Placebo: 5.74 ±2.47	Fin: 26.70 ±9.26 Placebo: 20.12 ±7.85			Fin: 2.76 ±2.05 Placebo: 2.95 ±2.59			