Additional file 3: Details of included studies

Author	Condition	Methods	Blinding	Baseline entry criteria	Patients	Finasteride Daily dose (mg)	Control	Duration	Efficacy outcomes Mean change from baseline	Efficacy outcomes Absolute values	Efficacy according to prostate size: finasteride	Adverse events	Discontinuations	AUR, surgery, prostate cancer	Quality score
Abrams et al, 1999	BPH	Randomised, double blind, parallel group, placebo control. Assessments at baseline, 9 & 12 months. Compliance monitored by tablet count.	Double	Enlarged prostate by DRE Lower urinary tract symptoms Objective evidence of outlet obstruction (pressure flow) Mean symptom score shows moderate / severe at baseline	Mean symptom score (AUA) at baseline: Fin: 19.4 ± 6.3 Placebo: 17.4 ± 6.8 Mean age: 67 years	5 mg (n=81) At 9 & 12 mth n=69	Placebo (n=40) At 9 mth n=37	12 months	Total symptom score (AUA): Fin: Baseline 19.4 ± 6.3; 12 mth -4.8 (no SD) Placebo: Baseline 17.4 ± 6.8; 12 mth -3.3 (no SD) Max urinary flow (mL/s): Fin: Baseline 7.6 ± 2.4; 12 mth +1.0 ± 2.5 Placebo: Baseline 7.1 ±2.0; 12 mth -0.1 ±1.5 Free flow max (mL/s): Fin: Baseline 10.0 ± 4.2; 12 mth +2.0 ± 5.8 Placebo: Baseline 9.1 ± 3.7; 12 mth -0.5 ± 2.7 Prostate volume (cc): Fin: Baseline 45.1; 12 mth -8.9 Placebo: Baseline 44.8; 12 mth +1.8	Symptom score (AUA): Fin: Baseline 19.4 ± 6.3; 12 mth 14.6 Placebo: Baseline 17.4 ± 6.8; 12 mth 14.1 Max urinary flow (mL/s): Fin: Baseline 7.6 ± 2.4; 12 mth 8.6 Placebo: Baseline 7.1 ±2.0; 12 mth 7.0 Free flow max (mL/s): Fin: Baseline 10.0 ± 4.2; 12 mth 12.0 Placebo: Baseline 9.1 ± 3.7; 12 mth 9.05 Prostate volume (cc): Fin: Baseline 45.1; 12 mth 36.2 Placebo: Baseline 44.8; 12 mth 46.6	Mean change from baseline at 12 mth: Maximum urinary flow rate: Prostate >40 cc (large): -1.6 (95% CI 0.2 to 3.0) Prostate <40 cc (small): +0.7 (95% CI -0.6 to 2.0)	No data	Total: Finasteride (12) Placebo (3) Adverse events: Finasteride (3) Placebo (3) Lack of efficacy: None	No data	R=1 DB=1 W=1
Andersen et al, 1995	BPH	Multicentre, randomised, double blind, parallel group, placebo control. 1 mth single blind placebo run-in before randomisation. Assessments at baseline, 12 & 24 mth with additional 4 mthly visits.	Double	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)	5 mg (n=353) Completed (287)	Placebo (n=354) Completed (290)	24 months	Total Boyarsky symptom score (0-54): Fin: Baseline 13.4; 3 mth -1.0; 6 mth -1.3; 12 mth -1.5; 18 mth -1.9; 24 mth -2.0 (95% CI -2.6 to -1.3) Placebo: Baseline 13.1; 3 mth -0.6; 6 mth -0.5; 12 mth -0.3; 18 mth 0.0; 24 mth 0.2 (CI -0.7 to 0.3) Max urinary flow rate (mL/s): Fin: Baseline10.2; 3 mth 1.0; 6 mth 1.5; 12 mth 1.4; 18 mth 1.6; 24 mth 1.5 (CI 1.1 to 1.9) Placebo: Baseline 10.5; 3 mth 0.4; 6 mth 0.25; 12 mth -0.1; 18 mth 0.5; 24 mth -0.3 (CI 0.7 to 0.0) Mean urinary flow rate (mL/s): Fin: Baseline 5.2; 24 mth 0.6 (CI 0.4 to 0.9) Placebo: Baseline 5.5; 24 mth -0.3 (CI -0.5 to -0.1) Prostate volume: Fin: Baseline 40.6; 24 mth -7.8 (-19.2%, CI -22.4 to -15.9) Placebo: Baseline 41.7; 24 mth -4.8 (-11.5%, CI 4.8 to 18.1)	Total Boyarsky symptom score (0-54): Fin: Baseline 13.4; 3 mth 12.4; 6 mth 12.1; 12 mth 11.9; 18 mth 11.6; 24 mth 11.4 Placebo: Baseline 13.1; 3 mth 12.5; 6 mth 12.5; 12 mth 12.8; 18 mth 13.4; 24 mth 13.3 Max urinary flow rate (mL/s): Fin: Baseline10.2; 3 mth 11.2; 6 mth 11.7; 12 mth 11.6; 18 mth 11.8; 24 mth 11.7 Placebo: Baseline 10.5; 3 mth 10.9; 6 mth 10.75; 12 mth 10.4; 18 mth 10.7; 24 mth 10.2 Mean urinary flow rate (mL/s): Fin: Baseline 5.2; 24 mth 5.8 Placebo: Baseline 5.5; 24 mth 5.2 Prostate volume: Fin: Baseline 40.6; 24 mth 32.8 Placebo: Baseline 41.7; 24 mth 36.9	No data	No differences between groups except for sexual dysfunction. Sexual dysfunction: Fin (55) Placebo (30)	Total discontinued: Finasteride (66) Placebo (64) Discontinued because of adverse events: Finasteride (39) Placebo (30) Discontinued because of lack of efficacy: Fin (13) Placebo (22)	No data	R=1 DB=1 W=1
Beisland HO et al, 1992	BPH	Multicentre, randomised, double blind, parallel group, placebo control with open label extension. 1 mth single blind placebo run-in before randomisation. Double blind: 24 wks. Assessments at baseline, 12, 24 wks Open label: Additional 12-18 mth on finasteride. No washout.	Double	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) Max urinary flow (mL/s): Fin: 8.0 ± 3.0 Placebo: 7.6 ± 3.1	5 mg (n=94)	Placebo (n=88)	6 months	Total Boyarsky symptom score (0-36): Fin: 8.8 ± 6.1; 12 wks -2.0; 24 wks -2.5 Placebo: 7.8 ± 4.9; 12 wks -0.7; 24 wks -1.2 Obstructive symptom score: Fin: 2.2 ± 4.0; 12 wks -1.6; 24 wks -2.0 Placebo: 1.1 ± 3.3; 12 wks -0.6; 24 wks 0.7 Max urinary flow rate (mL/s); Fin: Baseline 8.0 ±3.0; 12 wks 1.1; 24 wks 1.6 Placebo: Baseline 7.6 ±3.1; 12 wks 0.7; 24 wks 1.1 Median prostate volume (cm3): Fin: 44.2 ± 22.4; 24 wks -9.9 (22.5%) Placebo: 43.8 ± 24.1; 24 wks -0.4 (1.0%)	Total Boyarsky symptom score (0-36; 12 wks): Fin: 8.8 ± 6.1; 12 wks 6.8; 24 wks 6.3 Placebo: 7.8 ± 4.9; 12 wks 7.1; 24 wks 6.6 Obstructive symptom score: Fin: 2.2 ± 4.0; 12 wks 0.6; 24 wks 0.2 Placebo: 1.1 ± 3.3; 12 wks 0.5; 24 wks 1.8 Max urinary flow rate (mL/s); Fin: Baseline 8.0 ±3.0; 12 wks 9.1; 24 wks 9.6 Placebo: Baseline 7.6 ±3.1; 12 wks 8.3; 24 wks 8.7 Median prostate volume (cm3): Fin: 44.2 ± 22.4; 24 wks 34.3 Placebo: 43.8 ± 24.1; 24 wks 43.4	Number with ≥20% shrinkage in prostate volume at 24 wks: Fin (50) Placebo (16)	Serious: Fin (10) Placebo (1) One drug-related Sexual dysfunction (drug-related): Fin (5) Placebo (4) Headache Fin (9) Placebo (6)	Total discontinued: Fin (6) Placebo (3) Discontinued because of adverse events: Fin (6) Placebo (1) Discontinued because of lack of efficacy: No data	No data	R=1 DB=1 W=1

Author	Condition	Methods	Blinding	Baseline entry criteria	Patients	Finasteride Daily dose (mg)	Control	Duration	Efficacy outcomes Mean change from baseline	Efficacy outcomes Absolute values	Efficacy according to prostate size: finasteride	Adverse events	Discontinuations	AUR, surgery, prostate cancer	Quality score
Byrnes et al, 1995	BPH	Double blind, randomised, placebo controlled trial. Men attending community-based urology clinics for treatment of BPH. 1 mth single-blind placebo run-in. Patients with Moderate/severe symptoms at end of run-in & more than 80% compliance were randomised. Study visits were at 3 mth intervals. AUA symptom score. Compliance assessed by tablet count.	Double	Moderate / severe (1.9% pts had mild symptoms with finasteride & 2.2% with placebo) Enlarged prostate on DRE	2917 patients enrolled. Efficacy population: 2342 Safety population: 2417 Aged ≥45 years Mainly Caucasian Clinical diagnosis of BPH with prostate enlargement.	5 mg (n=1821)	Placebo (n=596)	12 months	AUA symptom score: Fin: Baseline not provided 3 mth -3.4; 6 mth -4.2; 9 mth -4.3; 12 mth -4.8 Placebo: Baseline not provided; 3 mth -2.5; 6 mth -3..3; 9 mth -3.2; 12 mth -3.3	Baseline not provided - no data	No data	Any AE: Fin (57.9%, 920) Placebo (58.6%, 349) Serious AE: Fin (11.6%,211) Placebo (12.2%, 73) Impotence: Fin (6.8%, 124) Placebo (3.2%, 19) Libido decrease: Fin (3.1%, 49) Placebo (1.2%, 7) Ejaculation disorder: Fin (2.3%, 37) Placebo (0.5%, 3) Sexual dysfunction at baseline: Fin (36.6%, 666) Placebo (33.7%, 201)	Total discontinued: Fin (9.4%, 171) Placebo (20.5%, 122) Discontinuation because of adverse effects; Fin (5.7%, 104) Placebo (4.7%, 28) Discontinuation because of lack of efficacy: Fin (3.5%, 64) Placebo (4.0%, 24)	TURP-total: Fin (1.6%, 29) Placebo (1.3%, 8) Acute urinary retention: Fin (0.6%, 11) Placebo (0.7%, 4) Worsening of BPH/lack of improvement: Fin (1.0%, 18) Placebo (0.7%, 4) Prostate cancer: Fin (0.3%, 5) Placebo (0.3%, 2)	R=1 DB=1 W=1
Carraro et al, 1996	BPH	Randomised, double blind, active controlled trial, parallel groups. Assessments at baseline, 6, 13 & 26 wks by same investigator. AUA symptom score.	Double	AUA ≥6, urinary flow 4-15 mL/s Clinical BPH by DRE	1098 randomised Completed trial: 951 (Fin 484, permixon 467) Mean age 64 years (range 49-88) Mean body mass index: 26 (range 17-38)	5 mg (n=545)	Permixon (serenoa repens) (n=553)	26 weeks	AUA symptom score: Fin: Baseline 15.7 ±5.7; 6 wks -3.5; 13 wks -5.2; 26 wks -6.2 Permixon: Baseline 15.7 ±5.8; 6 wks -3.4; 13 wks -4.7; 26 wks -5.8 Max urinary flow rate (mL/s): Fin: Baseline 10.8 ±2.8; 6 wks 1.7 (16%); 13 wks 2.4 (22%); 26 wks 3.34 (30%) Permixon: Baseline 10.6 ±2.8; 6 wks 1.6 (15%); 13 wks 2.1 (19.5%); 26 wks 2.7 (25%) Prostate volume (ml): Fin: Baseline 44.0 ±20.6; 6 wks no data; 13 wks 37.0; 26 wks 37.0 Permixon: Baseline 43.0 ±19/6; 6 wks no data; 13 wks -40.0; 26 wks -40.0	AUA symptom score: Fin: Baseline 15.7 ±5.7; 6 wks 12.2; 13 wks 10.5; 26 wks 9.5 ±5.5 Permixon: Baseline 15.7 ±5.8; 6 wks 12.3; 13 wks 11.0; 26 wks 9.9 ±5.4 Max urinary flow rate (mL/s): Fin: Baseline 10.8 ±2.8; 6 wks 12.5; 13 wks 13.2; 26 wks 14.0 ±7.4 Permixon: Baseline 10.6 ±2.8; 6 wks 12.2; 13 wks 12.7; 26 wks 13.3 ±6.7 Prostate volume (ml): Fin: Baseline 44.0 ±20.6; 6 wks no data; 13 wks 36.96; 26 wks 36.96 Permixon: Baseline 43.0 ±19/6; 6 wks no data; 13 wks 39.99; 26 wks 39.99	No data	Decreased libido: Fin (3.0%, 16) Permixon (2.2%, 12) Impotence: Fin (2.8%, 15) Permixon (1.5%, 8) Ejaculatory disorder: None reported	Total discontinued: Fin (61) Permixon (86) Discontinued because of adverse effects: Fin (14) Permixon (28) Discontinued because of lack of efficacy: Fin (2) Permixon (0)	Urinary retention: Fin (0.6%, 3) Permixon (1.3%, 7)	R=2 DB=1 W=1
Debruyne et al, 1998 ALFIN study	BPH	Randomised, double blind, active controlled trial, multicentre, parallel groups. 2 wk single blind, placebo run-in. Assessments at baseline, 1, 3 & 6 mth. AUA symptom score.	Double	AUA score ≥7 Qmax between 5-15 mL/s No threshold for prostate volume	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 of symptoms: about 3.5 years	5 mg (n=344)	Alfuzosin 10 mg daily (n=358) Combination (n=349) No placebo	6 months	AUA total symptom score: Fin: Baseline 15.5 ±5.2; 3 mth -4.5; 6 mth -5.2 ±5.7 Alf: Baseline 15.3 ±5.5; 3 mth -5.3; 6 mth -6.3 ±5.8 Combination: Baseline 15.6 ±5.7; 3 mth -5.8; 6 mth -6.1 ±5.6 Max urinary flow rate (mL/s): Fin: Baseline 9.8 ±2.6; 3 mth 1.8; 6 mth 1.8 ±4.5 Alf: Baseline 9.7 ±2.8; 3 mth 2.1; 6 mth 1.8 ±3.8 Combination: Baseline 10.1 ±3.5; 3 mth 2.4; 6 mth 2.3 ±4.7 Prostate volume (ml): Fin: Baseline 40.9 ±23.5; 6 mth -4.3 ±15.0 Alf: Baseline 41.4 ±25.7; 6 mth -0.2 ±14.3 Combination: Baseline 41.1 ±22.6; 6 mth -4.9 ±12.4	AUA total symptom score: Fin: Baseline 15.5 ±5.2; 3 mth 11.0; 6 mth 10.3 Alf: Baseline 15.3 ±5.5; 3 mth 10.0; 6 mth 9.0 Combination: Baseline 15.6 ±5.7; 3 mth 9.8; 6 mth 9.5 Max urinary flow rate (mL/s): Fin: Baseline 9.8 ±2.6; 3 mth 8.0; 6 mth 8.0 Alf: Baseline 9.7 ±2.8; 3 mth 7.6; 6 mth 7.9 Combination: Baseline 10.1 ±3.5; 3 mth 12.5; 6 mth 12.4 Prostate volume (ml): Fin: Baseline 40.9 ±23.5; 6 mth 36.3 Alf: Baseline 41.4 ±25.7; 6 mth 41.2 Combination: Baseline 41.1 ±22.6; 6 mth 36.2 % with ≥50% improvement in symptoms at 6 mth: Fin: 33% Alf: 43% Combination: 42%	No data	Any adverse effect: Fin (26%, 89) Alf (27%, 97) Combination (26%, 91) Serious adverse effects: Fin (2.9%, 10) Alf (1.7%, 6) Combination (2.3%, 8) Ejaculation failure: Fin (5) Alf (0) Combination (3) Impotence: Fin (22) Alf (8) Combination (26) Libido decreased: Fin (6) Alf (2) Combination (7)	Total discontinued: Fin (39) Alf (40) Combination (54) Discontinued because of adverse effects: Fin (18) Alf (25) Combination (24) Discontinued because of lack of efficacy: Fin (2) Alf (3) Combination (2)	AUR: Fin (2) Alf (3) Combination (2)	R=1 DB=1 W=1

Author	Condition	Methods	Blinding	Baseline entry criteria	Patients	Finasteride Daily dose (mg)	Control	Duration	Efficacy outcomes Mean change from baseline	Efficacy outcomes Absolute values	Efficacy according to prostate size: finasteride	Adverse events	Discontinuations	AUR, surgery, prostate cancer	Quality score
Finasteride study group, 1993 International study	BPH	Multicentre, randomised, double blind, placebo controlled, parallel groups. 2-wk placebo run-in. Periodic assessments. Boyarsky symptom scale	Double	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	1 mg (n=249) 5 mg (n=246)	Placebo (n=255)	12 months	Boyarksy total symptom score: Fin 1 mg: Baseline 18.7 ±6.0; 3 mth -2.2; 6 mth -2.9; 9 mth -2.8; 12 mth -2.7 Fin 5 mg: Baseline 18.6 ±6.0; 3 mth -2.5; 6 mth -3.1; 9 mth -3.4; 12 mth -3.4 Placebo: Baseline 18.2 ±5.9; 3 mth -1.9; 6 mth -2.2; 9 mth -2.1; 12 mth -2.0 Max urinary flow rate (mL/s): Fin 1 mg: Baseline 8.8 ±3.7; 3 mth 0.75; 6 mth 1.6; 9 mth 1.6; 12 mth 1.8 Fin 5 mg: Baseline 9.2 ±4.0; 3 mth 1.0; 6 mth 1.2; 9 mth 1.25; 12 mth 1.4 Placebo: Baseline 8.6 ±3.4; 3 mth 0.2; 6 mth 0.75; 9 mth 0.4; 12 mth 0.4 Prostate volume (cm3) median: Fin 1 mg: Baseline 47.5 ±22.5; 3 mth -7.6 (-16%); 6 mth -6.65 (-14%); 12 mth -11.4 (-24%) Fin 5 mg: Baseline 47.0 ±20.8; 3 mth -8.9 (-19%); 6 mth -9.9 (-21%); 12 mth -10.3 (-22%) Placebo: Baseline 46.3 ±23.4; 3 mth -2.3 (-5%); 6 mth -1.8 (-4%); 12 mth -1.8 (-4%)	Median Boyarksy symptom score: Fin 1 mg: Baseline 18.7 ±6.0; 3 mth 16.5; 6 mth 15.8; 9 mth 15.9; 12 mth 16.0 Fin 5 mg: Baseline 18.6 ±6.0; 3 mth 16.1; 6 mth 15.5; 9 mth 15.2; 12 mth 15.2 Placebo: Baseline 18.2 ±5.9; 3 mth 16.3; 6 mth 16.0; 9 mth 16.1; 12 mth 16.2 Max urinary flow rate (mL/s): Fin 1 mg: Baseline 8.8 ±3.7; 3 mth 9.55; 6 mth 10.46; 9 mth 10.4; 12 mth 10.6 Fin 5 mg: Baseline 9.2 ±4.0; 3 mth 10.2; 6 mth 10.4; 9 mth 10.45; 12 mth 10.6 Placebo: Baseline 8.6 ±3.4; 3 mth 8.8; 6 mth 9.35; 9 mth 9.0; 12 mth 9.0 Prostate volume (cm3) median: Fin 1 mg: Baseline 47.5 ±22.5; 3 mth 39.9; 6 mth 41.0; 12 mth 36.1 Fin 5 mg: Baseline 47.0 ±20.8; 3 mth 38.1; 6 mth 37.1; 12 mth 39.7 Placebo: Baseline 46.3 ±23.4; 3 mth 44.0; 6 mth 44.5; 12 mth 44.5	No data	Impotence: Fin 1 mg (10; 4.0%) Fin 5 mg (12; 4.9%) Placebo (1; 0.4%) No other data presented. Rate of adverse effects was similar between groups. Most impotence was of mild-moderate severity	Fin 5 mg: 1 patient withdrew because of impotence. No other data provided on withdrawals.	Prostate surgery for BPH: Fin 1 mg (1) Fin 5 mg (3) Placebo (4) Acute urinary retention: Fin 1 mg (2) Fin 5 mg (3) Placebo (3)	R=1 DB=1 W=1
Gormley et al, 1992 North American study	BPH	Randomised, double blind, placebo controlled, parallel groups. 1 mth single blind placebo run-in. Assessed mthly by same investigator. Compliance rated by tablet count. Boyarsky symptom scale	Double then open	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	1 mg (n=298) 5 mg (n=297)	Placebo (n=300)	12 months	Boyarsky symptom score: Fin 1 mg: Baseline 10.6 ±5.7; 3 mth -1.4; 6 mth -1.8; 9 mth -1.7; 12 mth -1.6 (-9%) Fin 5 mg: Baseline 10.2 ±5.5; 3 mth -1.95; 6 mth -1.95; 9 mth -1.9; 12 mth -2.5 (-21%) Placebo: Baseline 9.8 ±5.3; 3 mth -1.5; 6 mth -1.25; 9 mth -1.2; 12 mth -1.0 (-2%) Max urinary flow rate (mL/s): Fin 1 mg: Baseline 10.6 ±5.7; 3 mth 1.8; 6 mth 1.9; 9 mth 2.1; 12 mth 2.1 (23%) Fin 5 mg: Baseline 10.2 ±5.5; 3 mth 2.0; 6 mth 1.9; 9 mth 2.5; 12 mth 2.7 (22%) Placebo: Baseline 9.8 ±5.3; 3 mth 0.2; 6 mth 0.1; 9 mth 0.3; 12 mth 0.2 (8%) Prostate volume (ml): Fin 1 mg: Baseline 60.9 ±34.3; 12 mth -10.2 Fin 5 mg: Baseline 58.6 ±30.5; 12 mth -11.1 Placebo: Baseline 61.0 ±36.5; 12 mth -11.2	Boyarsky symptom score: Fin 1 mg: Baseline 10.6 ±5.7; 3 mth 9.2; 6 mth 8.8; 9 mth 8.9; 12 mth 9.0 Fin 5 mg: Baseline 10.2 ±5.5; 3 mth 8.25; 6 mth 8.25; 9 mth 8.3; 12 mth 7.7 Placebo: Baseline 9.8 ±5.3; 3 mth 8.3; 6 mth 8.55; 9 mth 8.6; 12 mth 8.8 Max urinary flow rate (mL/s): Fin 1 mg: Baseline 10.6 ±5.7; 3 mth 12.4; 6 mth 12.5; 9 mth 12.7; 12 mth 12.7 Fin 5 mg: Baseline 10.2 ±5.5; 3 mth 12.2; 6 mth 12.1; 9 mth 12.7; 12 mth 12.9 Placebo: Baseline 9.8 ±5.3; 3 mth 10.0; 6 mth 9.9; 9 mth 10.1; 12 mth 10.0 Prostate volume (ml): Fin 1 mg: Baseline 60.9 ±34.3; 12 mth 49.1 ±26.6 Fin 5 mg: Baseline 58.6 ±30.5; 12 mth 47.5 ±23.6 Placebo: Baseline 61.0 ±36.5; 12 mth 59.8 ±39.4	No data	Ejaculatory disorder: Fin 1 mg (4.4%, 13) Fin 5 mg (4.4%, 13) Placebo (1.7%, 5) Impotence: Fin 1 mg (5.0%, 15) Fin 5 mg (3.4%, 10) Placebo (1.7%, 5) Orgasm dysfunction: Fin 1 mg (0.3%, 9) Fin 5 mg (0.7%, 2) Placebo (0.3%, 1) Decreased libido Fin 1 mg (6.0%, 18) Fin 5 mg (4.7%, 14) Placebo (1.3%, 4)	Total discontinued: Fin 1 mg (28) Fin 5 mg (40) Placebo (37) Discontinued because of adverse effects: Fin 1 mg (14) Fin 5 mg (16) Placebo (18) Discontinued because of lack of efficacy: Fin 1 mg (4) Fin 5 mg (12) Placebo (9)	TURP: Fin 1 mg (4) Fin 5 mg (3) Placebo (3) One man had a radical prostatectomy for prostate cancer	R=1 DB=1 W=1
Isotalo et al, 2001	BPH plus acute urinary retention.	Patients were catheterised & had a stent implanted. Those able to void were randomised. Double blind, placebo controlled, parallel group trial. AUA symptom score.	Double	Ability to void after catheterisation and stent implant. No further details.	55 patients enrolled. 19 completed the trial. AUR related to BPH Mean age 71 years (range 52-89) Mean prostatic volume by TRUS was 66 (17-150) ml.	5 mg (n=26)	Placebo (n=29)	18 mth	AUA total symptom score: No significant changes between or within groups. No further details. Max urinary flow rate (mL/s): Fin: Baseline 6.2; 6 mth 1.2; 12 mth 5.2; 18 mth 2.1 Placebo: Baseline 7.0; 6 mth -1.1); 12 mth 1.2; 18 mth 0.4 Prostate volume (ml): Fin: Baseline 62; 6 mth no data; 12 mth -16; 18 mth -20 Placebo: Baseline 70; 6 mth no data; 12 mth -15; 18 mth -6	AUA total symptom score: No significant changes between or within groups. No further details. Max urinary flow rate (mL/s): Fin: Baseline 6.2; 6 mth 7.4; 12 mth 11.4; 18 mth 8.3 Placebo: Baseline 7.0; 6 mth 5.9; 12 mth 8.2; 18 mth 7.6 Prostate volume (ml): Fin: Baseline 62; 6 mth no data; 12 mth 46; 18 mth 42 Placebo: Baseline 70; 6 mth no data; 12 mth 55; 18 mth 64	No data	4 AEs reported, other than urinary problems. None were sexual dysfunction.	Total discontinued: Fin (18) Placebo (18) Discontinued because of adverse effects: n=2* Discontinued because of lack of efficacy: n=29* *not stated per group	No data	R=1 DB=2 W=1
Kirby et al, 1992	BPH	Randomised, double blind, placebo controlled, parallel groups. 1 wk placebo run-in. Assessed mthly. Last observation carried forward for drop-outs (DB phase only). Boyarsky symptom scale	Double	Mean Boyarsky symptom score ≥8. Confirmed obstruction. Prostate volume by TRUS.	Outflow obstruction due to BPH Mean age 64 years (range 48-87)	5 mg (n=29) 10 mg (n=16)	Placebo (n=21)	3 mth	Boyarsky total symptom score: Fin 5 mg: Baseline 19.3; 3 mth -4.0 Fin 10 mg: Baseline 16.9; 3 mth -2.3 Placebo: Baseline 18.8; 3 mth -3.5 Max urinary flow rate (mL/s): Fin 5 mg: Baseline 7.2; 3 mth 3.3 Fin 10 mg: Baseline 9.3; 3 mth 1.5 Placebo: Baseline 11.1; 3 mth 0.9 Prostate volume (cm3): Fin 5 mg: Baseline 49.7; 3 mth -2.3 fin 10 mg: Baseline 54.3; 3 mth -2.2 Placebo: Baseline 37.7; 3 mth -2.0	Boyarsky total symptom score: Fin 5 mg: Baseline 19.3; 3 mth 15.3 Fin 10 mg: Baseline 16.9; 3 mth 14.6 Placebo: Baseline 18.8; 3 mth 15.3 Max urinary flow rate (mL/s): Fin 5 mg: Baseline 7.2; 3 mth 10.5 Fin 10 mg: Baseline 9.3; 3 mth 10.8 Placebo: Baseline 11.1; 3 mth 10.0 Prostate volume (cm3): Fin 5 mg: Baseline 49.7; 3 mth 47.4 fin 10 mg: Baseline 54.3; 3 mth 52.1 Placebo: Baseline 37.7; 3 mth 35.7	No data	Few and minor. Fin 5 mg: Chest infection (1) Impotence (1) Fin 10 mg: Rash (1)	Total discontinued: 12 Discontinued because of adverse effects: 4 No further details provided	No data	R=1 DB=2 W=1

Author	Condition	Methods	Blinding	Baseline entry criteria	Patients	Finasteride Daily dose (mg)	Control	Duration	Efficacy outcomes Mean change from baseline	Efficacy outcomes Absolute values	Efficacy according to prostate size: finasteride	Adverse events	Discontinuations	AUR, surgery, prostate cancer	Quality score
Lepor et al, 1996 VA cooperative study.	BPH	Randomised, double blind, parallel group, placebo control. Assessments at baseline, 9 & 12 months. 1 mth single blind placebo run-in Compliance monitored by tablet count. AUA symptom score. Periodic assessments including 13, 26, 32 & 52 wks.	Double	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)	5 mg (n=310)	Placebo (n=305) Terazosin 10 mg (n=305) Combination (n=309)	12 months	AUA total symptom score: Fin: Baseline 16.2 ± 5.4; 12 mth -3.2 Terazocin: Baseline 16.2 ±5.5; 12 mth -6.1 Combination: Baseline 15.9 ±5.7; 12 mth -6.2 Placebo: Baseline 15.8 ± 5.5; 12 mth -2.6 Peak urinary flow rate at 4-52 wks: Fin: Baseline 10.6 ±2.5.; 1.6 Terazocin: Baseline 10.5 ±2.6; 2.7 Combination: Baseline 10.4 ±2.7; 3.2 Placebo: Baseline 10.4 ±2.6; 1.4 Prostate volume (cm3): Fin: Baseline 36.2 ±1.0; 12 mth -6.1 Terazocin: Baseline 37.5 ±1.1; 12 mth 0.5 Combination: Baseline 37.2 ±1.1; 12 mth -7.0 Placebo: Baseline 38.4 ±1.3; 12 mth+0.5	AUA total symptom score: Fin: Baseline 16.2 ± 5.4; 12 mth 13.0 Terazocin: Baseline 16.2 ±5.5; 12 mth 10.1 Combination: Baseline 15.9 ±5.7; 12 mth 9.7 Placebo: Baseline 15.8 ± 5.5; 12 mth 13.2 Peak urinary flow rate at 4-52 wks: Fin: Baseline 10.6 ±2.5.; 12.2 Terazocin: Baseline 10.5 ±2.6; 2.7 Combination: Baseline 10.4 ±2.7; 3.2 Placebo: Baseline 10.4 ±2.6; 11.8 Prostate volume (cm3): Fin: Baseline 36.2 ±1.0; 12 mth 30.1 Terazocin: Baseline 37.5 ±1.1; 12 mth 38 Combination: Baseline 37.2 ±1.1; 12 mth 30.2 Placebo: Baseline 38.4 ±1.3; 12 mth 38.9	No data	Any AE: No data Impotence: Fin (29); Placebo (14); Terazosin (18); Combination (29) Ejaculatory disorder: Fin (6); Placebo (4); Terazosin (1); Combination (21) Decreased libido: Fin (14); Placebo (4); Terazosin (8); Combination (15)	Total discontinued: Fin (67) Terazosin (49) Combination (55) Placebo (51) Discontinued because of adverse effects: Fin (15) Terazosin (18) Combination (24) Placebo (5) Discontinued because of lack of efficacy: No data	Need for surgery: Fin (5) Terazosin (2) Combination (2) Placebo (4)	R=2 DB=1 W=1
Lukkarinen et al, 1999	BPH post-balloon dilation	Randomised, double blind, placebo controlled, parallel groups. 4 wk placebo run-in. Assessed at 3. 6, 9, 12, 18 & 24 mth. Last observation carried forward for drop-outs (DB phase only). Boyarsky symptom scale	Double	Moderate to severe symptoms of BPH treated by balloon dilatation; 50% reduction in symptoms. Enlarged prostate on DRE &TRUS	Completed trial (24mth): Fin (27) Placebo (25) Mean age: 65 years (range 50-82)	5 mg (n=33)	Placebo (n=31)	24 months	Total Boyarsky symptom score: Fin: Baseline 7.0; 24 mth 3.2 Placebo: Baseline 7.0; 24 mth 4.4 Obstructive symptom score: Fin: Baseline not provided; 24 mth 1.4 Placebo: Baseline not provided; 24 mth 2.6 Max urinary flow rate (mL/s): Fin: Baseline 13.7 ±6.1; 24 mth 0.2 Placebo: Baseline 13.3 ±6.0; 24 mth -2.1 Prostate volume (cm3): Fin: Baseline 41.9 ±9.8; 24 mth -13.1 Placebo: Baseline 46.7±12.3; 24 mth -3.9	Total Boyarsky symptom score: Fin: Baseline 7.0; 24 mth 10.2 Placebo: Baseline 7.0; 24 mth 11.4 Max urinary flow rate (mL/s): Fin: Baseline 13.7 ±6.1; 24 mth 13.9 ±5.6 Placebo: Baseline 13.3 ±6.0; 24 mth 11.2 ±5.4 Prostate volume (cm3): Fin: Baseline 41.9 ±9.8; 24 mth 28.8 ±11.8 Placebo: Baseline 46.7±12.3; 24 mth 42.8 ±19.4	No data	No data	Total discontinued: Fin (6) Placebo (6) Discontinued because of adverse effects: Fin (3) Placebo (3) Discontinued because of lack of efficacy: Fin (2) Placebo (2)	No data	R=1 DB=1 W=1
Marberger et al, 1998 PROWESS	BPH	Multicentre, randomised, double blind, placebo controlled trial. Screening: 1.5 mth & 1 mth placebo run-in before randomisation. Compliance assessed by tablet count.	Double	Moderate symptoms (at least 2) Enlarged prostate on DRE	3270 patients enrolled; 2902 randomised. Clinical diagnosis of BPH 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 Completed trial: Fin (1119; 77.9%) Placebo (1092; 75%)	5 mg (n=1450)	Placebo (n=1452)	24 months	Total Boyarsky symptom score (0-54): Fin: Baseline 14.5 ± 7.3; 3 mth -1.8; 6 mth -2.4; 12 mth -2.9; 18 mth -3.15; 24 mth -3.15 Placebo: Baseline 14.3 ±7.2; 3 mth -1.2; 6 mth -1.8; 12 mth -1.85; 18 mth -1.7; 24 mth -1.5 Max urinary flow rate (mL/s): Fin: Baseline 11.2 ±5.9; 4 mth 0.9; 24 mth 1.4 Placebo: Baseline 10.9 ±3.6; 4 mth 0.6; 24 mth 0.8 Prostate volume (cm3): Fin: Baseline 38.7 ± 20.1; 3 mth -1.6 (-4.0%); 6 mth -3.1 (-8%); 12 mth -4.6 (-12%); 18 mth -5.8 (-15%); 24 mth -5.8 (-15%) Placebo: Baseline 39.2 ± 20.2; 3 mth 0.8 (2.0%); 6 mth 1.2 (3%); 12 mth 1.9 (5%); 18 mth 3.1 (8%); 24 mth 3.5 (+9%)	Total Boyarsky symptom score (0-54): Fin: Baseline 14.5 ± 7.3; 3 mth 12.7; 6 mth 12.1; 12 mth 11.6; 18 mth 11.35; 24 mth 11.35 Placebo: Baseline 14.3 ±7.2; 3 mth 14.1; 6 mth 12.5; 12 mth 12.45; 18 mth 12.6; 24 mth 12.8 Max urinary flow rate (mL/s): Fin: Baseline 11.2 ±5.9; 4 mth 12.1; 24 mth 12.6 Placebo: Baseline 10.9 ±3.6; 4 mth 11.5; 24 mth 11.7 Prostate volume (cm3): Fin: Baseline 38.7 ± 20.1; 3 mth 37.1; 6 mth 35.6; 12 mth 31.0; 18 mth 32.8; 24 mth 30.5 Placebo: Baseline 39.2 ± 20.2; 3 mth 40.0; 6 mth 40.4; 12 mth 39.0; 18 mth 42.3; 24 mth 40.9	Finasteride: Prostate volume >40 cm^3 (n=394) Prostate volume ≤40 cm^3 (n=680) Trend for greater response in patients with prostates >40 cm^3 for total symptom score (placebo adjusted figures only provided)	3168 patients available for safety analysis. Any AE: Fin (761); Placebo (786) Serious AE: Fin (149); Placebo (186) Death from AE: Fin (16); Placebo (15) Libido decreased: Fin (63); Placebo (44) Ejaculation disorder: Fin (33)' Placebo (9) Impotence: Fin (104); Placebo (74)	Total discontinued: Fin (331) Placebo (360) Discontinued because of adverse effects: Fin (108) Placebo (137) Discontinued because of lack of efficacy: Fin (50) Placebo (64)	Acute urinary retention / catheterisation at 24 mth: Fin: 24 (1.7%) Placebo: 54 (3.7%) BPH related surgery at 24 mth: Fin: 66 (4.6%) Placebo: 111 (7.6%)	R=2 DB=2 W=1
Marks et al, 1997	BPH + obstruction	Randomised, double blind, placebo controlled, parallel groups. 1 mth single blind placebo run-in. Assessed at 6 wks, 3 & 6 mth. Nurse telephoned to determine compliance etc. AUA questionnaire	Double	Symptomatic BPH (chronic symptoms of bladder outlet obstruction) AUA ≥9 (moderate / severe) Prostate enlargement on rectal examination	Completed study: Fin (26) Placebo (13) Mean age: 64 years (range 52-78) Mainly Caucasian	5 mg (n=26)	Placebo (n=15)	6 months DB	Total IPPS symptom score: Fin: Baseline 17.0 ±5; 3 mth -6.0; 6 mth -7.0 Placebo: Baseline 16.0 ±2; 3 mth -5.5; 6 mth -4.5 Max urinary flow rate (cc/s): Fin: Baseline 13.0 ±7; 3 mth 0.0; 6 mth 2.0 Placebo: Baseline 12.0 ±5; 3 mth 2.5; 6 mth 4.0	Total IPPS symptom score: Fin: Baseline 17.0 ±5; 3 mth 11.0; 6 mth 10.0, 6 mth 10.0 Placebo: Baseline 16.0 ±2; 3 mth 10.5; 6 mth 11.5 Max urinary flow rate (cc/s): Fin: Baseline 13.0 ±7; 3 mth 13.0; 6 mth 15.0 Placebo: Baseline 12.0 ±5; 3 mth 14.5; 6 mth 16.0	No data	No data	Total discontinued: Fin (0) Placebo (2)	No data	R=1 DB=2 W=1

Author	Condition	Methods	Blinding	Baseline entry criteria	Patients	Finasteride Daily dose (mg)	Control	Duration	Efficacy outcomes Mean change from baseline	Efficacy outcomes Absolute values	Efficacy according to prostate size: finasteride	Adverse events	Discontinuations	AUR, surgery, prostate cancer	Quality score
McConnell et al, 1998 PLESS	BPH	Multicentre, randomised, double blind, placebo controlled, parallel groups. 1 mth single blind placebo run-in. Assessed every 4 mth. AUA symptom scale	Double	Moderate/severe symptoms Enlarged prostate on DRE Mean prostate volume 55 +/-25 ml Qmax 11 +/- 4	3040 patients enrolled Completed 4 yrs: Fin (1000) Placebo (883) Mean age: 64 yrs 95% Caucasian	5 mg (n=1524)	Placebo (n=1516)	48 months	AUA symptom score (all patients): Fin: Baseline 15 ± 6; 3 mth -1.1; 6 mth -1.7; 12 mth -2.7; 18 mth -2.6; 24 mth -2.9; 36 mth -2.9; 48 mth -3.2 Placebo: Baseline 15 ±6; 3 mth -0.7; 6 mth -1.3; 12 mth -1.6; 18 mth -1.5; 24 mth -1.4; 36 mth -1.4; 48 mth -1.2 Max urinary flow rate (mL/s): Fin: Baseline 11.0 ±4.0; 3 mth 0.8; 6 mth 0.9; 12 mth 1.25; 18 mth 1.65; 24 mth 1.6; 36 mth 1.65 48 mth 1.9 Placebo: Baseline 11.0 ±4.0; 3 mth 0.25; 6 mth 0.3; 12 mth 0.3; 18 mth 0.3; 24 mth 0.4; 36 mth 0.0; 48 mth 0.25 Prostate volume (ml): Fin: Baseline 55 ±26; 3 mth -2.75 (-5%); 6 mth -4.4 (-8%); 12 mth -9.4 (-17%); 18 mth -9.9 (-18%); 24 mth -9.9(-18%); 36 mth -9.4 (-17%); 48 mth -9.4 (-17%) Placebo: Baseline 54 ±25; 3 mth 1.1 (2%); 6 mth 1.6 (3%); 12 mth 2.7 (5%); 18 mth 3.8 (7%); 24 mth 4.3 (8%); 36 mth 5.9 (11%); 48 mth 7.0 (13%)	Quasi-AUA symptom score (all patients): Fin: Baseline 15 ± 6.0; 3 mth 13.9; 6 mth 13.3; 12 mth 12.7; 18 mth 12.3; 24 mth 12.1; 36 mth 12.1; 48 mth 11.8 Placebo: Baseline 15 ±6.0; 3 mth 14.3; 6 mth 13.7; 12 mth 13.4; 18 mth 13.5; 24 mth 13.6; 36 mth 13.6; 48 mth 13.8 Max urinary flow rate (mL/s): Fin: Baseline 11.0 ±4.0; 3 mth 11.8; 6 mth 11.9; 12 mth 12.25; 18 mth 12.65; 24 mth 12.6; 36 mth 112.65; 48 mth 12.9 Placebo: Baseline 11.0 ±4.0; 3 mth 11.325; 6 mth 11.3; 12 mth 11.3; 18 mth 11.3; 24 mth 11.4; 36 mth 11.0; 48 mth 11.25 Prostate volume (ml): Fin: Baseline 55 ±26; 3 mth 52.25; 6 mth 50.6; 12 mth 45.6; 18 mth 45.1; 24 mth 45.1; 36 mth 45.6; 48 mth 45.6 Placebo: Baseline 54 ±25; 3 mth 55.1; 6 mth 55.6; 12 mth 56.7; 18 mth 57.8; 24 mth 58.3; 36 mth 59.9; 48 mth 61.0	No data	Adverse effects at 1 yr Decreased libido (DL): Fin (6.4%, 98); Placebo (3.4%, 52) Impotence: Fin (8.1%, 123); Placebo (3.7%, 56) Ejaculation disorder (ED): Fin (0.8%, 12); Placebo (0.1%, 2) Adverse effects at yrs 2-4: DL: Fin (2.6%, 40); Placebo (2.6%, 39) Impotence: Fin (5.1%, 78); Placebo (5.1%, 77) ED: Fin (0.2%, 3); Placebo (0.1%, 2)	Total discontinued: Fin (524) Placebo (633) Discontinued because of adverse effects: Fin (176) Placebo (166) Discontinued because of lack of efficacy: Fin (99) Placebo (104)	Surgery or catheterisation for acute urinary retention: Fin (100; 7%) Placebo (199; 13%) Surgery: Fin (69; 5%) Placebo (152; 10%) Acute urinary retention: Fin (42; 3%) Placebo (99; 7%) Prostate cancer: Overall incidence was 5% in each group	R=2 DB=1 W=1
Nickel et al, 1996 PROSPECT	BPH	Multicentre, randomised, double blind, placebo controlled, parallel groups. Placebo run-in Assessments at 4 mth intervals.	Double	Moderate symptoms . Enlarged prostate by DRE	613 patients. Mean age: 63 years (range 46-80) Obstruction symptom score: Fin: Baseline 10.2 ±4.8 Placebo: Baseline 10.7 ±4.5 Completed trial: Fin (246) Placebo (226)	5 mg (n=310)	Placebo (n=303)	24 months	Boyarsky total symptom score: Fin: Baseline 15.8 ±7.6; 3 mth -1.3; 6 mth -1.5; 12 mth -1.8; 18 mth -1.9; 24 mth -2.1 Placebo: Baseline 16.6 ±7.2; 3 mth -1.3; 6 mth -1.4; 12 mth -0.95; 18 mth -0.8; 24 mth -0.8 Mean urinary flow rate (mL/s): Fin: Baseline 11.1 ±3.7; 6 mth 0.35; 12 mth 0.6; 18 mth 0.65; 24 mth 0.7 Placebo: Baseline 10.9 ±3.5; 6 mth 0.13; 12 mth 0.2; 18 mth 0.18; 24 mth 0.2 Max urinary flow rate (mL/s) Fin: Baseline 11.1; 3mth 0.6; 6 mth 0.75; 12 mth 1.0; 18 mth 1.25; 24 mth 1.3 Placebo: Baseline 10.9; 3mth 0.4; 6 mth 0.5; 12 mth 0.25; 18 mth 0.3; 24 mth 0.3 Prostate volume (cm3): Fin: Baseline 44.1 ±23.5; 12 mth -7.9 (18%); 24 mth -9.3 (21%) Placebo: Baseline 45.8 ±22.4; 12 mth 2.7 (6%); 24 mth 3.8 (8.4%)	Boyarksy total symptom score: Fin: Baseline 15.8 ±7.6; 3 mth 14.5; 6 mth 14.3; 12 mth 14.0; 18 mth 13.9; 24 mth 13.7 Placebo: Baseline 16.6 ±7.2; 3 mth 15.3; 6 mth 15.2; 12 mth 15.65; 18 mth 15.8; 24 mth 15.8 Mean urinary flow rate (mL/s): Fin: Baseline 11.1 ±3.7; 6 mth 11.45; 12 mth 11.7; 18 mth 11.75; 24 mth 11.8 Placebo: Baseline 10.9 ±3.5; 6 mth 11.03; 12 mth 11.1; 18 mth 11.08; 24 mth 11.1 Max urinary flow rate (mL/s) Fin: Baseline 11.1; 3 mth 11.7; 6 mth 11.85; 12 mth 12.1; 18 mth 12.35; 24 mth 12.4 Placebo: Baseline 10.9; 3 mth 11.3; 6 mth 11.4; 12 mth 11.15; 18 mth 11.2; 24 mth 11.2 Prostate volume (cm3): Fin: Baseline 44.1 ±23.5; 12 mth 36.2; 24 mth 34.8 Placebo: Baseline 45.8 ±22.4; 12 mth 48.5; 24 mth 49.6	No data	Any adverse effect: Fin (251) Placebo (246) Ejaculation disorder: Fin (24) Placebo (5) Impotence: Fin (49) Placebo (19) Libido decreased: fin (31) Placebo (19)	Total discontinued: Fin (64) Placebo (77) Discontinued because of adverse effects: Fin (28) Placebo (40) Discontinued because of lack of efficacy: Fin (16) Placebo (19)	Acute urinary retention or urological intervention (eg TURP): Fin (19; 6.1%) Placebo (31 (10.2%) Prostate cancer: Fin (3) Placebo (6)	R=2 DB=2 W=1
Sokeland & Albrecht, 1997	BPH	Randomised, double blind, multicentre, placebo controlled, parallel groups. AUA total symptom score	Double	Qmax >15 mL/s, voided volume ≥150 ml	Number enrolled: 543	1 capsule (n=244)	2 capsules Pro 120/160 (Sabal + urtica extract) (n=245)	48 weeks	AUA total symptom score: Fin: Baseline 11.8 ±6.6; 12 wks -2.9; 24 wks -3.8; 36 wks -5.0; 48 wks -5.6 Pro 160/120: Baseline 11.3 ±6.5; 12 wks -2.6; 24 wks -3.1; 36 wks -4.1; 48 wks -4.8 Mean change from baseline Max urinary flow rate (mL/s): Fin: Baseline 12.7 ±4.5; 12 wks 1.9 ±5.4; 24 wks 2.4 ±6.3; 36 wks 2.6 ±6.8; 48 wks 2.8 ±6.6 Pro 160/120: Baseline 12.7 ±4.4; 12 wks 1.6 ±5.4; 24 wks 1.9 ±5.6; 36 wks 1.9 ±5.9; 24 wks 2.0 ±6.4; 48 wks 2.4	AUA total symptom score: Fin: Baseline 11.8 ±6.6; 12 wks 8.9 ±6.1; 24 wks 8.0 ±5.7; 36 wks 6.8 ±5.3; 48 wks 6.2 ±5.2 Pro 160/120: Baseline 11.3 ±6.5; 12 wks 8.7 ±6.0; 24 wks 8.2 ±5.8; 36 wks 7.2 ±5.7; 48 wks 6.5 ±5.8 Max urinary flow rate (mL/s): Fin: Baseline 12.7 ±4.5; 12 wks 14.6; 24 wks 15.1; 36 wks 15.3; 48 wks 15.5 Pro 160/120: Baseline 12.7 ±4.4; 12 wks 14.3; 24 wks 14.6; 36 wks 14.6; 24 wks 14.7; 48 wks 15.1	No data	Erectile dysfunction: Fin (7) Pro 160/120: (1)	Unknown	No data	R=1 DB=2 W=?
[Stoner et al, 1992 a]	BPH	Randomised, double blind, placebo controlled, parallel groups.	DB	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)	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	Prostate volume: Fin 5 mg: Baseline 71.6 ±39.2, 3 mth -16.0 (-22.8% ±17.9) Placebo: Baseline 79.7 ±37.0, 3 mth -3 (-4.1% ±19.0)	Prostate volume: Fin 5 mg: Baseline 71.6 ±39.2, 3 mth 55.5 Placebo: Baseline 79.7 ±37.0, 3 mth 76.7	No data	See study 2 since all safety data was combined	See study 2 Discontinued because of adverse effects (study 1): 5 patients	No data	R=1 DB=1 W=1

Author	Condition	Methods	Blinding	Baseline entry criteria	Patients	Finasteride Daily dose (mg)	Control	Duration	Efficacy outcomes Mean change from baseline	Efficacy outcomes Absolute values	Efficacy according to prostate size: finasteride	Adverse events	Discontinuations	AUR, surgery, prostate cancer	Quality score
[Stoner et al, 1992 b]	BPH	Randomised, double blind, placebo controlled, parallel groups.1 wk placebo run-in	DB	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)	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	Boyarsky Total Symptom score: Fin 1/5mg: Baseline 18.4 (no SD); 12 wks -1.85; 24 wks -2.5 Placebo: Baseline 16.5 (no SD); 12 wks -0.85; 24 wks -0.5 Max urinary flow rate (cc/s): Fin 1/5mg: Baseline 9.5 (no SD); 12 wks 2.0; 24 wks 3.5 Placebo: Baseline 9.2 (no SD); 12 wks -1.0; 24 wks 0.0 Prostate volume: Fin 1 mg: Baseline 86.3 ±64.5; 12 wks -12.6 (-14.6% ±16.8); 24 wks -21.1 (-24.4% ±17.5) Fin 5 mg: Baseline 66.6 ±40.4; 12 wks -11.5 (-17.3% ±11.8); 24 wks -18.4 (-27.7% ±10.8) Placebo: Baseline 63.5 ±30.6; 12 wks -3.6 (-5.6% ±20.8); 24 wks -3.3 (-5.2% ±21.1)	Boyarsky Total Symptom score: Fin 1/5mg: Baseline 18.4 (no SD); 12 wks 16.55; 24 wks 15.9 Placebo: Baseline 16.5 (no SD); 12 wks 15.65; 24 wks 16.0 Max urinary flow rate (cc/s): Fin 1/5mg: Baseline 9.5 (no SD); 12 wks 11.5; 24 wks 13.0 Placebo: Baseline 9.2 (no SD); 12 wks 8.2; 24 wks 9.2 Prostate volume: Fin 1 mg: Baseline 86.3 ±64.5; 12 wks 73.7; 24 wks 65.2 Fin 5 mg: Baseline 66.6 ±40.4; 12 wks 55.1; 24 wks 48.2 Placebo: Baseline 63.5 ±30.6; 12 wks 59.9; 24 wks 60.2	No data	Study 1 & 2 combined: Serious adverse effects: Fin (13) Placebo (1) Headache: Fin (11) Placebo (0)	Combined data from studies 1 & 2: Total discontinued: Fin (11) Placebo (1) Discontinued because of adverse effects (study 2): 7 patients	No data	R=1 DB=1 W=1
Tammela & Kontturi, 1993	BPH with bladder outlet obstruction	Randomised, double blind, placebo controlled, parallel groups. Boyarsky symptom score	Double	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)	5 mg (n=19)	Placebo (n=17)	6 months	Boyarsky total symptom score: Fin: Baseline 10.4; 6 mth -3.7 Placebo: Baseline 9.8; 6 mth -1.1 Max urinary flow rate (mL/s): Fin: Baseline 7.7 ±2.3; 6 mth +2.4 Placebo: Baseline 8.8 ±3.3; 6 mth +1.1	Max urinary flow rate (mL/s): Fin: Baseline 7.7 ±2.3; 6 mth 10.3 ±4.1 Placebo: Baseline 8.8 ±3.3; 6 mth 9.9 ±2.9 Boyarsky total symptom score: Fin: Baseline 10.4; 6 mth 6.7 Placebo: Baseline 9.8; 6 mth 7.7	No data	No data	None	No data	R=1 DB=1 W=1
Tenover et al, 1997	BPH	Multicentre, randomised, double blind, placebo controlled, parallel groups. 1 mth single blind placebo run-in. Assessed at 3 mth intervals. Compliance by pill count. AUA symptom score	Double	Moderate to severe symptoms of clinically diagnosed BPH. Enlarged prostate on DRE	Number patients enrolled: 2808; 2315 randomised Mean age 63 years (range 45-94) Mainly Caucasian	5 mg (n=1589 per protocol) 1736 analysed for safety	Placebo (n=523 per protocol) 579 analysed for safety	12 months	AUA symptom score at 12 mth: Fin: Baseline 19.03; 3 mth -3.0; 6 mth -4.2; 12 mth -4.96 (no SD) Placebo: Baseline 18.35; 3 mth -2.5; 6 mth -3.5; 12 mth -3.71 (no SD)	AUA symptom score at 12 mth: Fin: Baseline 19.03; 3 mth 16.03; 6 mth 14.8; 12 mth 14.07 Placebo: Baseline 18.35; 3 mth 15.8; 6 mth 14.8 ; 12 mth 14.64 Patient global rating of improvement at 12 mth: Fin (51.9%) Placebo (42.9%)	No data	1736 (Fin) & 579 (placebo) patients in safety analyses. Any adverse effect: Fin (75.4%, 1309) Placebo (72.5%, 412) Serious adverse effect: Fin (13%, 226) Placebo (13.3%, 77) Any sexual dysfunction: Fin (13.8%, 240) Placebo (6.6%, 38) Impotence: Fin (8.1%, 141) Placebo (3.8%, 22) Libido decreased: Fin (5.4%, 94) Placebo (3.3%, 19) Ejaculation disorder: Fin (4.0%, 69) Placebo (0.9%, 5)	Total discontinued: Fin (16.6%, 263) Placebo (16.4%, 86) Discontinued because of adverse effects: Fin (7.1%, 113) Placebo (6.6%, 35) Discontinued because of lack of efficacy: Fin (2.5%, 40) Placebo (2.4%, 13)	1736 (Fin) & 579 (placebo) patients in safety analyses. Acute urinary retention: Fin (0.2%, 3) Placebo (0.4%, 2) TURP: Fin (0.8%, 14) Placebo (0.9%, 5) Prostate cancer: Fin: 0.5% Placebo: 0.5% BPH worse/no improvement: Fin: 0.5% Placebo: 0.5%	R=1 DB=1 W=1
Yu et al, 1995	BPH	Randomised, double blind, placebo controlled, parallel groups.2 wk washout. TRUS & DRE to confirm BPH & rule out prostate cancer. Assessed at 2 mth intervals. AUA symptom score	Double	Bothersome symptoms of BPH.	Number patients enrolled: 50 Number patients completed: 46 Mean age: 65 years (range 50-82)	5 mg (n=25)	Placebo (n=25)	6 months	AUA symptom score: Fin: Baseline 19.45 ±6.63; 3 mth -1.95 (-10%); 6 mth -5.98 (-30% ±20) Placebo: Baseline 16.68 ±4.06; 3 mth -1.17(-7%); 6 mth -2.36 (-12 ±20) Max urinary flow rate (mL/s): Fin: Baseline 11.19 ±2.47; 6 mth 1.42 (20% ±26) Placebo: Baseline 11.44 ±4.76; 6 mth 0.17 (3% ±19) Prostate volume: Fin: Baseline 26.70 ±9.26; 6 mth -4.08 (-14% ±11) Placebo: Baseline 20.12 ±7.85; 6 mth 1.26 (1%±12)	AUA symptom score: Fin: Baseline 19.45 ±6.63; 3 mth 17.5; 6 mth 13.47 ±4.36 Placebo: Baseline 16.68 ±4.06; 3 mth 15.5; 6 mth 14.32 ±4.26 Prostate volume: Fin: Baseline 26.70 ±9.26; 6 mth 22.62 ±7.76 Placebo: Baseline 20.12 ±7.85; 6 mth 21.38 ±9.88 Max urinary flow rate (mL/s): Fin: Baseline 11.19 ±2.47; 6 mth 12.61 ±3.3 Placebo: Baseline 11.44 ±4.76; 6 mth 11.61 ±4.68	No data	Adverse effects were few & minor. Finasteride: decreased libido (2) Dry mouth (1) Placebo: Light-headedness (1) Gastric irritation (1)	Total number discontinued: Fin (1) Placebo (3) Discontinued because of lack of efficacy: Fin (0) Placebo (2) Discontinued because of adverse effects: None	No data	R=1 DB=1 W=1