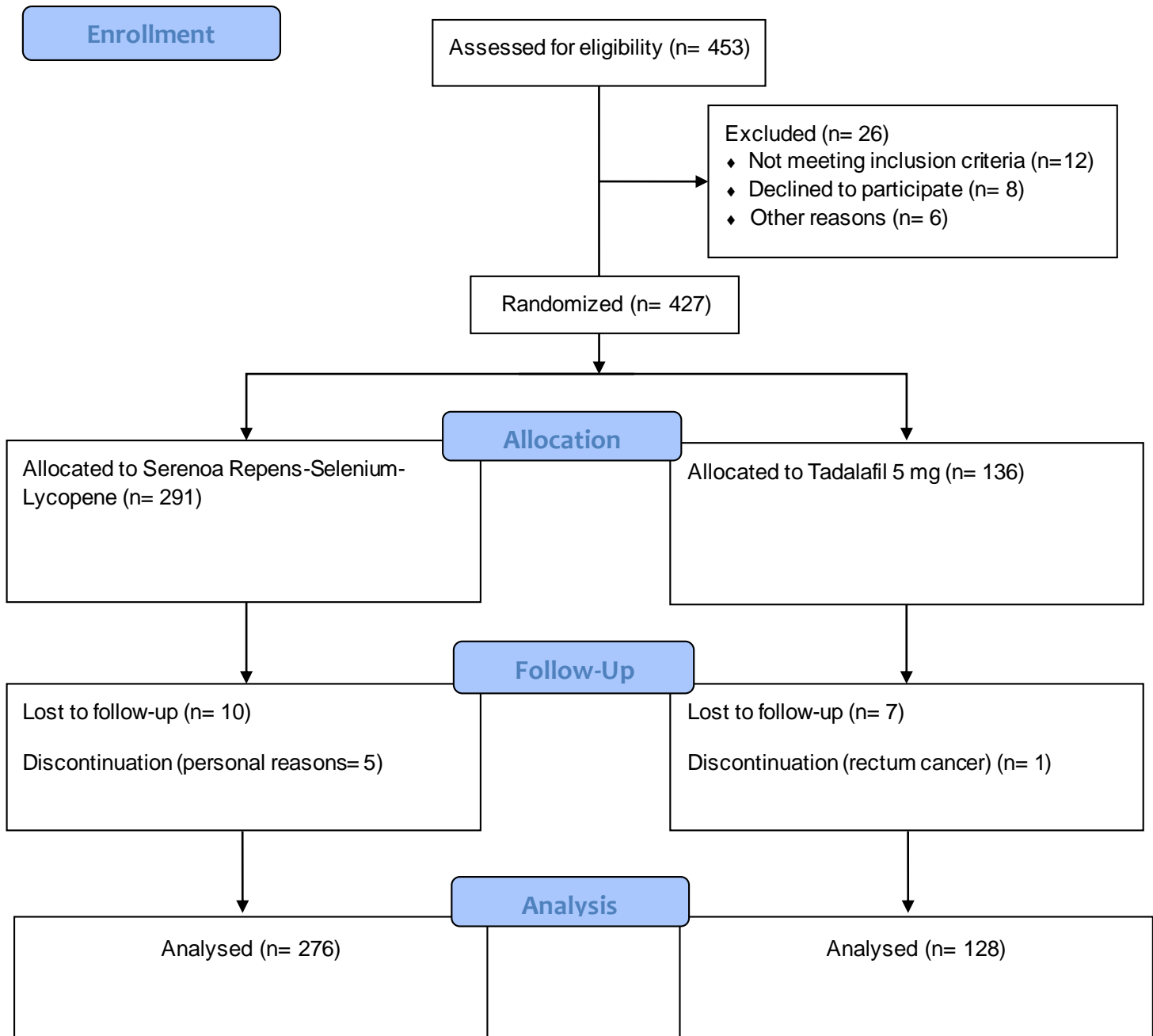


Participant flow



Baseline characteristics

Table 1. Baseline characteristics of the patients.		
	Group A Serenoa repens + selenium + lycopene (n=276)	Group B Tadalafil 5 mg (n=128)
Age, median (SD)	64.0 (6.3)	63 (6.9)
PSA (ng/ml), median (SD)	1.8 (1.0)	1.9 (1.1)
Prostate Volume (cc), median (SD)	45.0 (13.1)	45.0 (13.0)
Peak flow (ml/s), median (SD)	12.0 (2.2)	12.0 (2.0)
Post-void volume (ml), median (SD)	40.0 (33.5)	40.0 (33.2)
IPSS, median (SD)	17.0 (4.6)	18.0 (4.0)
IIEF-5, median (SD)	18.0 (4.7)	17.5 (4.7)
QoL, median (SD)	3.0 (1.0)	3.0 (0.8)

Outcome measures

Table 2. Median change of primary and secondary outcomes from baseline to 6 months.			
	Group A Serenoa repens + selenium + lycopene (n=276)	Group B Tadalafil 5 mg (n=128)	p-value
IPSS, median change from baseline (95% CI)	-3.0 (-5.0, -2.0)	-3.0 (-4.0, -1.0)	<0.01*
Percentage change of IPSS, median change from baseline (95% CI)	-20.0 (-28.42, -10.0)	-16.7 (-25.27, -5.26)	0.03*
Decrease of 3 point of IPSS, no (%)	164 (59.4)	67 (52.3)	0.18 [†]
Decrease of 25% of IPSS, no (%)	87 (31.5)	38 (29.7)	0.71 [†]
Qmax, ml/s, median change from baseline (95% CI)	2.0 (1.0, 3.4)	1.6 (0.60, 3.0)	<0.01*
Percentage change of Qmax, %, median change from baseline (95% CI)	18.2 (7.69, 33.33)	14.25 (5.54, 26.25)	0.02*
Increase of 3 point of Qmax, no (%)	104 (38.2)	36 (28.1)	0.04 [†]
Increase of 30% of Qmax, no (%)	108 (39.6)	35 (27.3)	<0.01 [†]
Post-void volume, ml, median change from baseline (95% CI)	-15.0 (-30.0, 0.0)	-13.5 (-30.0, 0.0)	0.44 [‡]
IIEF-5, median change from baseline (95% CI)	1.0 (0.0, 2.0)	4.0 (2.0, 6.0)	<0.01 [‡]
Prostate volume, cc, median change from baseline (95% CI)	-2.0 (0.33)	0.0 (0.06)	0.30 [‡]
PSA, ng/ml, median change from baseline (95% CI)	-0.1 (-0.3, 0.09)	-0.06 (-0.28, 0.10)	0.95 [‡]
IPSS-Qol, median change from baseline (95% CI)	-2.0 (-3.0, 0.0)	-2.0 (-3.0, -0.25)	<0.05
*non-inferiority test			
[‡] superiority test			
[†] Chi-square test			

Adverse events

Table 3. Reported TEAE in the two groups.			
	Group A Serenoa repens selenium + lycopene (n=276)	Group B Tadalafil 5 mg (n=128)	p-value
Total, n (%)	4 (1.44)	10 (7.81)	<0.01
Hypotension, (n)	1	1	
Headache, (n)	-	2	
Lumbar pain, (n)	-	2	
Asthenia, (n)	-	5	
Dysuria, (n)	3	-	