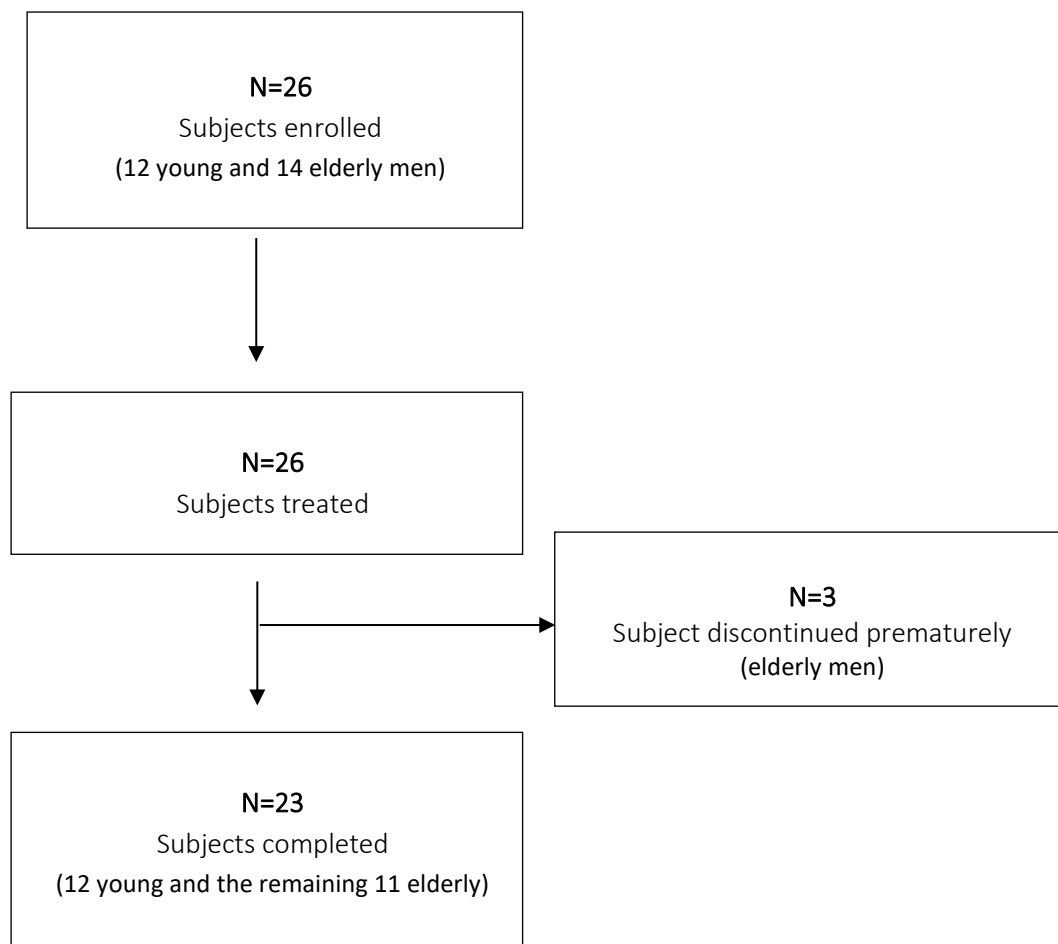


Participant flow



Baseline characteristics

Demographic data	Young - N=12	Elderly - N=14
Age (years)		
Mean $\pm$ SD	30.8 $\pm$ 7.3	68.1 $\pm$ 3.2
Median (range)	29.0 (22 – 45)	67.0 (65 – 75)
Body weight (kg)		
Mean $\pm$ SD	78.67 $\pm$ 9.97	76.56 $\pm$ 11.97
Range	76.20 (66.4 – 92.0)	73.80 (58.4 – 103.5)
Height (cm)		
Mean $\pm$ SD	175.9 $\pm$ 4.6	173.3 $\pm$ 6.0
Median (range)	177.5 (169 – 182)	172.5 (164 – 188)
BMI		
Mean $\pm$ SD	25.33 $\pm$ 2.18	25.44 $\pm$ 3.16
Median (range)	24.85 (21.9 – 28.4)	25.60 (19.7 – 29.5)
Race		
White – n (%)	10 (83.3)	14 (100)
Mulatto – n (%)	2 (16.7)	--
Ethnicity		
Hispanic, Latino or of Spanish origin – n (%)	6 (50)	--
Not Hispanic, Latino or of Spanish origin – n (%)	6 (50)	14 (100)

Outcome measures

The 3 derived PD parameters – $\Delta_{\max}$, $T_{\max}$, Δ_{mean} and AUEC_{0-t} – are summarized by hemodynamic parameter, treatment and age group in the table below.

	T1		T2		T3		P	
	Young	Elderly	Young	Elderly	Young	Elderly	Young	Elderly
SBP	N=12	N=12	N=12	N=14	N=12	N=12	N=12	N=11
$\Delta_{\max}$ (mmHg)	-11.09±8.55	-20.13±7.76	-13.08±7.57	-25.57±9.78	-13.42±8.81	-21.85±9.49	-7.28±4.40	-8.09±6.14
$T_{\max}$ (h)	2.00 (0.8-3.5)	1.63 (0.8-7.0)	2.00 (0.8-4.0)	1.88 (0.3-7.0)	2.13 (0.8-4.0)	3.38 (0.3-7.0)	2.38 (0.3-3.8)	0.75 (0.5-7.0)
Δ_{mean} (mmHg)	0.09±4.20	-7.83±5.76	-2.30±4.59	-12.20±8.64	-2.26±6.25	-8.69±8.06	3.84±3.46	3.25±6.20
AUEC_{0-t} (mmHg $\times$ h)	1133.68 ±74.74	1214.26 ±95.60	1121.65 ±54.62	1197.37 ±100.85	1144.34 ±69.11	1182.72 ±112.60	1181.38 ±74.80	1307.06 ±74.24
DBP								
$\Delta_{\max}$ (mmHg)	-12.93±5.06	-13.80±4.83	-14.10±8.33	-14.18±5.06	-11.17±7.48	-13.06±5.87	-8.92±6.55	-5.45±4.37
$T_{\max}$ (h)	1.88 (0.8-4.0)	1.50 (0.3-7.0)	3.13 (0.3-4.0)	1.63 (0.5-7.0)	1.75 (0.8-7.0)	2.13 (0.5-7.0)	2.38 (0.5-4.0)	2.75 (0.3-10.0)
Δ_{mean} (mmHg)	-1.63±3.05	-5.38±3.63	-3.13±5.03	-5.31±4.52	-0.74±5.26	-4.13±5.00	2.72±4.12	1.60±4.00
AUEC_{0-t} (mmHg $\times$ h)	675.22 ±60.25	773.75 ±71.53	662.10 ±66.24	768.08 ±74.12	676.75 ±73.36	763.38 ±81.40	719.77 ±69.21	838.16 ±48.71
Pulse rate								
$\Delta_{\max}$ (bpm)	24.44±4.61	13.10±4.21	21.83±11.34	17.19±6.39	24.74±15.21	18.58±7.79	21.13±7.61	13.84±6.62
$T_{\max}$ (h)	7.00 (2.8-10.0)	7.00 (3.8-10.0)	7.00 (0.5-10.0)	7.00 (0.3-10.0)	7.00 (3.5-10.0)	7.00 (7.0-10.0)	7.00 (1.3-10.0)	7.00 (5.0-10.0)
Δ_{mean} (bpm)	4.51±3.09	-0.48±2.07	3.70±4.43	1.24±2.16	1.11±7.70	-0.20±2.46	2.42±3.56	-0.57±4.79
AUEC_{0-t} (bpm $\times$ h)	693.75 ±80.02	624.87 ±61.74	688.17 ±92.41	668.34 ±76.12	707.01 ±94.68	645.59 ±66.59	677.82 ±78.90	636.70 ±74.52

Mean ($\pm$ SD) is presented except for $T_{\max}$, for which median (range) is presented; T1, T2, T3 and P: sildenafil IBSA 50, 75 and 100 mg and 100-mg matching placebo oral film; SBP: systolic blood pressure; DBP: diastolic blood pressure

Adverse events

Overview of TEAEs in young men. Safety set

Category	T1		T2		T3		P		Overall	
	N=12		N=12		N=12		N=12		N=12	
	AEs	Subjects	AEs	Subjects	AEs	Subjects	AEs	Subjects	AEs	Subjects
	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)
All TEAEs	0	0	1	1 (8.3)	2	2 (16.7)	1	1 (8.3)	4	3 (25.0)
Related	0	0	1	1 (8.3)	2	2 (16.7)	1	1 (8.3)	4	3 (25.0)
Not related	0	0	0	0	0	0	0	0	0	0
Leading to discontinuation	0	0	0	0	0	0	0	0	0	0
SAEs	0	0	0	0	0	0	0	0	0	0

T1, T2, T3 and P: sildenafil IBSA 50, 75 and 100 mg and 100-mg matching placebo oral film

Overview of TEAEs in elderly men. Safety set

Category	T1		T2		T3		P		Overall	
	N=12		N=14		N=12		N=11		N=14	
	AEs	Subjects	AEs	Subjects	AEs	Subjects	AEs	Subjects	AEs	Subjects
	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)
All TEAEs	6	3 (25.0)	3	1 (7.1)	2	2 (16.7)	0	0	11	4 (28.6)
Related	6	3 (25.0)	1	1 (7.1)	2	2 (16.7)	0	0	9	4 (28.6)
Not related	0	0	2	1 (7.1)	0	0	0	0	2	1 (7.1)
Leading to discontinuation	0	0	0	0	0	0	0	0	0	0
SAEs	0	0	0	0	0	0	0	0	0	0

T1, T2, T3 and P: sildenafil IBSA 50, 75 and 100 mg and 100-mg matching placebo oral film