

Baseline characteristics

Group (n)	Female	Male	Sessions	Mean Age (yrs)	Mean Evolution (mo)
Tibial stimulation 1 session (19)	7	12	Single	49.90 <u>+</u> 17.32	43 ±51.61
Tibial stimulation 6 sessions (15)	9	6	6	51.80 <u>+</u> 4.45	32.68 ± 10.08
Tibial stimulation 6 sessions and electromiography (14)	2	12	6	34.23±12.90	19.58±12.08
Placebo (13)	6+1*	7+2*	Single Sham	47.46± 18.22	62.31 ±19.09

No statistical differences between groups (p=0.163), nor between sexes (p=0.352, Mann-Whitney Rank Sum Test). * Placebo group corresponding to Third Group.

Table. Tibial stimulation 1 session versus Placebo

Tibial stimulation 1 session	Baseline	24hr	1 Month	3 Months	6 Months	Diff of means vs PLACEBO
Frequency	17.05± 2.10	8.26± 0.76	10.31± 0.83	10.63± 1.01	10.47± 0.89	
Diff of means		8.78	6.73	6.42	6.57	6.07
p Value		<0.001	<0.001	<0.001	<0.001	<0.001
Nocturia	5.31± 0.79	1.47± 0.29	2.26± 0.30	2.10± 0.27	2.26± 0.31	
Diff of means		3.84	3.05	3.21	3.05	2.22
p Value		<0.001	<0.001	<0.001	<0.001	0.012
Urgency	10.15± 1.61	1.57± 0.34	2.05± 0.33	2.10± 0.35	2.21± 0.47	
Diff of means		8.57	8.10	8.05	7.94	7.87
p Value		<0.001	<0.001	<0.001	<0.001	<0.001
Incontinence	1.42± 0.36	0.68± 0.24	0.94± 0.27	1.10± 0.25	1.15± 0.29	
Diff of means		0.73	0.47	0.31	0.26	0.27
p Value		0.059	0.223	0.415	0.497	0.694
Voided Volume	142.74	189.18	172.11	171.63	165.68	
	±89.01	±68.77	±74.72	±75.62	±78.48	
Diff of means		46.42	29.63	28.88	22.94	25.21
p Value		0.360	0.778	0.788	0.897	0.048

Table. Tibial stimulation 6 sessions versus Placebo

Tibial stimulation 6 sessions	Baseline	24hr	1 Month	3 Months	6 Months	Diff of means vs PLACEBO
Frequency	13.69±4.31	8.83±2.80	8.91±2.79	9.08±1.41	9.38±1.71	
Diff of means		4.86	4.77	4.61	4.30	3.18
p Value		<0.001	<0.001	<0.001	0.002	0.028
Nocturia	2.88±2.14	1.11±1.03	1.61±1.30	1.11±0.79	1.44±0.89	
Diff of means		1.77	1.27	1.77	1.44	0.96
p Value		0.005	0.081	0.005	0.035	0.119
Urgency	5.61±4.09	1.27±2.60	1.64±3.84	1.50±2.69	1.64±2.29	
Diff of means		4.33	3.97	4.11	3.97	3.11
p Value		0.004	0.011	0.008	0.011	0.059
Incontinence	1.05±1.59	0.11±0.35	0.14±0.35	0.22±0.56	0.36±0.61	
Diff of means		0.94	0.92	0.83	0.39	0.450
p Value		0.030	0.037	0.0.072	0.188	.065
Voided Volume	177.50 ±48.41	208.00 ±71.51	197.22 ±61.52	202.80 ±65.03	198.50 ±63.59	
Diff of means		31.38	19.72	25.30	21.00	12.97
p Value		0.698	0.927	0.836	0.909	0.056

Table. Tibial stimulation 6 sessions and electromiography versus Placebo

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Variable	ACTIVE	PLACEBO		
Age (years)	33.78±13.08	36.33±14.50		
Female	2	1		
Male	12	2		
Evolution	10.64±3.40	14.66±4.80		
Mean EMG	0.488 μV	0.153 μV		
Pre PTNS	±0.042	±0.035		
Mean EMG	0.365 μV	0.140 μV		
Trans PTNS	±0.040	±0.015		
Diferencia of means	0.123	0.013		
	±0.012	±0.020		
Significance Pre-Trans	p= 0.047	p= 0.725		

Table. Placebo

Tibial sham stimulation	Baseline	24hr	1 Month	3 Months	6 Months	Diff of
6 sessions						means
Frequency	10.92± 0.75	9.92± 0.82	10.84± 1.39	10.30± 1.06	11.84± 1.77	
Diff of means		1.00	0.07	0.61	-0.92	
p Value		0.506	0.969	0.756	0.641	
Nocturia	2.23± 0.23	1.61± 0.43	2.00± 0.42	1.76± 0.41	2.07± 0.48	
Diff of means		0.61	0.23	0.46	0.15	
p Value		0.390	0.747	0.519	0.830	
Urgency	1.69± 0.67	1.69± 0.71	1.30± 0.75	1.30± 0.68	1.61± 0.82	
Diff of means		0.0	0.38	0.38	0.07	
p Value		1.000	0.757	0.757	0.951	
Incontinence	.23± 0.23	0.23± 0.23	0.38± 0.24	0.38± 0.31	0.76± 0.44	
Diff of means		0.00	0.15	0.15	0.53	
p Value		1.000	0.743	0.743	0.251	
Voided Volume	196.20	205.70	190.56	191.69	183.28	
	±75.20	±97.60	±70.08	±76.53	±76.78	
Diff of means		9.50	5.63	4.50	12.91	
p Value		0.998	1.000	1.000	0.994	

Adverse events. There were no adverse events associated with this trial.