

Table 2

Timeline of visits/calls and measures through primary 6 month outcome.

	Baseline/ screening	Inject/ FSLP ^a	3 d call ^b	2 wk visit ^b	Implantation ^b	1 m visit ^c	2 m call ^c	3 m visit ^c	4 m call ^c	5 m call ^c	6 m visit ^c
Window	1–4 wk period		3 ± 2 d	7–14 d (InterStim)/ 10–14 d (Botox)	8–18 d (InterStim)	30 ± 10 d	61 ± 10 d	91 ± 10 d	122 ± 10 d	152 ± 10 d	183 ± 10 d
Consent	X										
Biomarker/DNA collection	X										
Hx/PE	X										
Timed up and go	X										
Urodynamic assessment	X										
Serum creatinine	X										
Preg test ^f		X									
Urine dip ^f	X	X ^d		X ^d		X ^d		X ^d			X ^d
PVR	X			X ^d		X ^d		X ^d			X ^d
Adv events/voiding assessment		X	X/X ^d	X/X ^d	X ^e	X/X ^d	X/X ^d	X/X ^d	X/X ^d	X/X ^d	X/X ^d
Bladder diary ^g	X			X		X	X	X	X	X	X
PGSC and OABq-SF	X (only OABq)					X	X	X	X	X	X
Icon programmer/device data ^e						X ^e		X ^e			X ^e
Iconic questionnaire ^e						X ^e					X ^e
IIQ-SF, UDI-SF, PISQ-12/R, Vaizey, Sandvik, life-space assessment, HUI-3	X										X
PGII and OAB-SATq											X
ConMeds	X	X	X	X	X	X	X	X	X	X	X

^a <2 months (61 days after completion baseline/screening phase).^b Relative to first injection or FSLP for those treated, to final decision to not treat for those not treated.^c Relative to first injection or final implantation/removal of device, to final decision to not treat for those not treated.^d Botox subjects only.^e InterStim subjects only.^f Also at before any subsequent reinjection or revision of surgery.^g Typically obtained during week prior to visit/call.