Report Title:	CA2017EU CLP 12-Month Clinical Study Report
Study Title:	A Clinical Study to Evaluate HF10™ Therapy in Patients with Chronic Intractable Leg Pain
Protocol Number:	CA2017 EU CLP
Sponsor:	Nevro Corp.
Reference Number:	CSR-00003
Report Version:	1.0
Report Date:	1st November 2021
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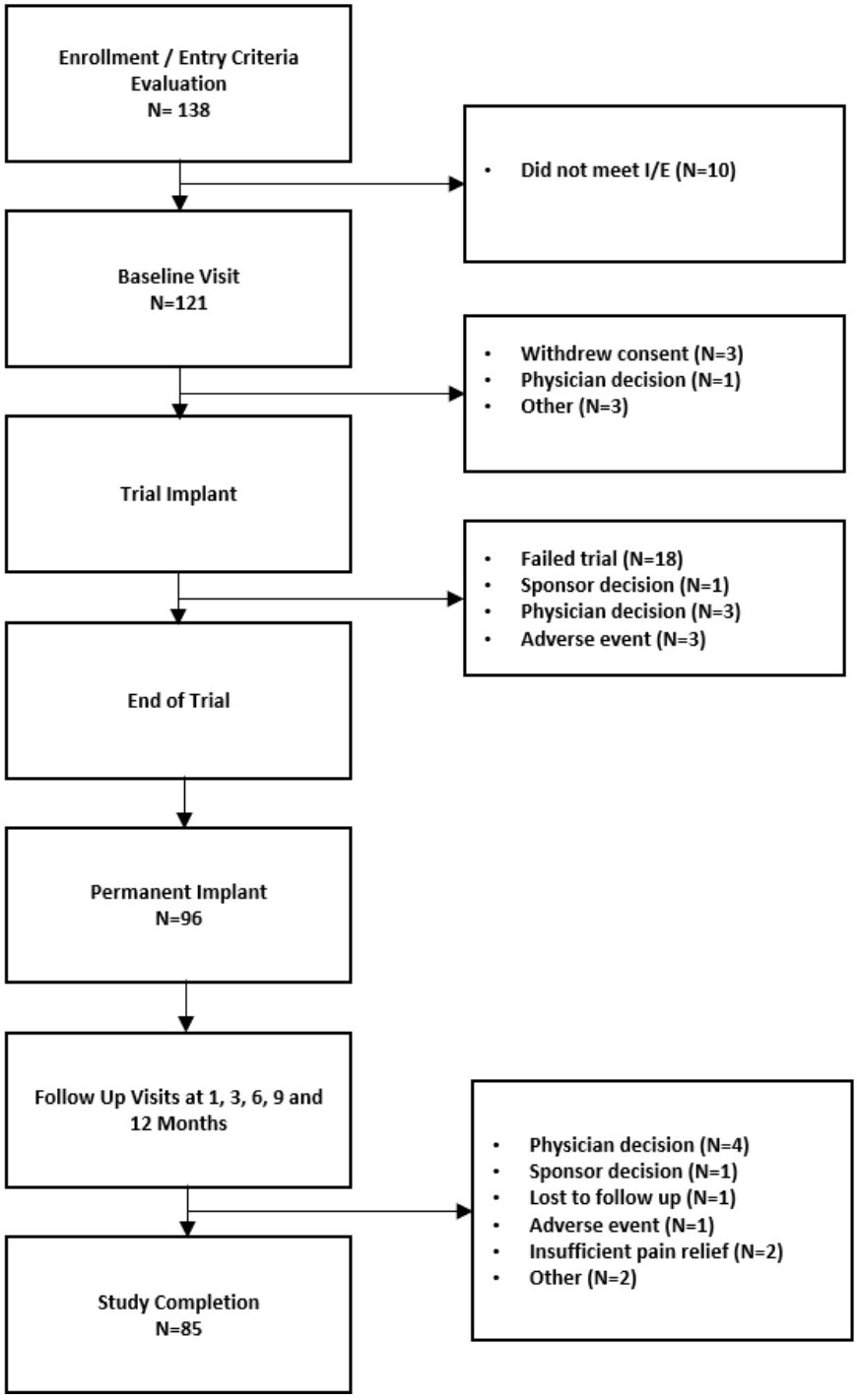
Report Version	Description	Report Date
1.0	12-Month Report	1st Nov 2021

Participant Flow



Baseline Characteristics

Characteristics	N=121
Gender *n* (%)	
Female	45 (37.2%)
Male	76 (62.8%)
Age (years) at enrolment	
Mean ± SD	51.7±11.5
Range	23.0 to 82.0
Years since diagnosis	
Mean ± SD	9.7±9
Range	1 to 42
Pain Diagnosis[a] *n* (%)	
Chronic intractable leg pain	120 (99.1%)
Chronic intractable back pain	105 (86.7%)
Pain Aetiology[b]	
Failed back surgery syndrome	114 (94.2%)
Degenerative disc disease	31 (25.6%)
Radiculopathy	45 (37.1%
Sacroiliac dysfunction	8 (6.6%)
Internal disc disruption / annular tear	12 (9.9%)
Neuropathic pain	56 (46.2%)
Other	6 (4.9%)
Spondylolisthesis	3 (2.4%)
Mild/mod spinal stenosis	8 (6.6%)
Lumbar facet-mediated pain	11 (9.1%)
Baseline VAS in cm	
Leg pain (mean ± SD)	7.8±1.2
Back pain (mean ± SD)	8±1.3
Baseline Oswestry Disability Index (mean±SD)	60±13.2
Baseline use of opioids *n* (%)	66 (54.5%)
Baseline EQ5D5L Health Status/Index Score (mean± SD)	45.1±22 0.183±0.256

Outcome Measures

Outcome Measure – Change from Baseline (change±SD)	**Time since permanent implantation**		
	3 Months	**6 Months**	**12 Months**
EQ5D5L: *Health Status*	20.6±24.6	21.8±27.7	20.4±25.7
EQ5D5L: *Index*	0.383±0.256	0.359±0.241	0.355±0.275
ODI	22.7±15.7	20.8±14.5	21.6±15.9
Opioid change: *n* (% decreased or eliminated)	26 (38.8%)	26 (40%)	26 (41.2%)
SF-MPQ-2: *total*	3.3±2.1	3±1.9	3±2.9
SF-MPQ-2: *continuous pain*	-3.3±2.4	-3.1±2.2	-3.2±3.1
SF-MPQ-2: *intermittent pain*	-3.0±2.5	-2.9±2.3	-2.9±3.3
SF-MPQ-2: *neuropathic pain*	-3.0±2.2	-2.9±2.1	-2.7±3.2
SF-MPQ-2: *affective descriptors*	-3.4±2.7	-3.2±2.6	-3.3±3.4
PSQ-3	8.5±9	9.8±8.9	9.1±9.5

EQ-5D-5L - European Quality of Life-5 Dimensions, ODI Oswestry Disability Index, SF-MPQ Short-Form McGill Pain Questionnaire, PSQ-3 Pain and Sleep Questionnaire

Patient global impression of change (PGIC) *n (%)*	**Time since permanent Implantation**	
	3 Months	**12 Months**
Very much improved	22 (24.4%)	29 (34.5%)
Much improved	42 (46.7%)	28 (33.3%)
Minimally improved	18 (20%)	24 (28.6%)
No change	4 (4.4%)	0 (0%)
Minimally worse	2 (2.2%)	1 (1.2%)
Much worse	2 (2.2%)	2 (2.4%)
Very much worse	0 (0%)	0 (0%)

Clinician global impression of change (CGIC) *n (%)*	**Time since permanent Implantation**	
	3 Months	**12 Months**
Very much improved	22 (24.4%)	23 (30.7%)
Much improved	48 (53.3%)	30 (40%)
Minimally improved	16 (17.8%)	20 (26.7%)
No change	3 (3.3%)	1 (1.3%)
Minimally worse	1 (1.1%)	1 (1.3%)
Much worse	0 (0%)	0 (0%)
Very much worse	0 (0%)	0 (0%)

Work status	**Baseline**	**Completion**
Working (full-time or part-time)	31 (27.7%)	30 (26.8%)
Retired	20 (17.9%)	25 (22.3%)
Unable to work due to leg / back pain	51 (45.5%)	42 (37.5%)
Unable to work due to health reasons other than leg / back pain	5 (4.5%)	9 (8%)
Not working (e.g. unemployed, home duties)	5 (4.5%)	6 (5.4%)
Total	112	112

Summary of All Adverse Events

	(N=138)	
	Number of AEs	**Number (%) of Subjects with AE**
All AEs	**186**	**84 (60.8%)**
AEs by relationship to study		
Not related	125	60 (43.4%)
Related	61	47 (34%)
Device related	28	15 (10.8%)
Procedure related	29	20 (14.4%)
Stimulation / Therapy	4	3 (2.1%)
AEs by severity		
Mild	125	78 (56.5%)
Moderate	48	33 (23.9%)
Severe	13	11 (7.9%)
AEs by outcome		
Resolved	141	47.1 (6.3%)
Ongoing	40	30 (21.7%)
Unknown	5	5 (3.6%)
Death	1	1 (0.8%)