

Now Enrolling: Clinical Trial of a Medical Device to Manage Pain Associated with CRPS

The TARGET study is a prospective, single arm, observational post-approval study designed to assess the continued safety and efficacy of dorsal root ganglion (DRG) stimulation for the management of lower body pain associated with CRPS. DRG therapy works by stimulating dorsal root ganglia (DRGs). These are structures along the spinal column made up of densely populated sensory nerves, and they act like traffic lights, regulating signals and sensations that travel through nerve fibers along the spinal column to the brain. The device is made up of a generator (a small device that sends out mild electrical pulses) leads (thin insulated wires that carry the electrical pulses to the DRG) and the patient controller, a handheld remote control that allows you to adjust the strength and location of stimulation. The generator and leads are implanted in your body but can be removed. DRG stimulation was approved by the FDA in February of 2016.

The TARGET study is currently enrolling patients across 40 sites in the United States. Patients between the ages of 22 and 75 years of age diagnosed with moderate to severe chronic intractable pain of the lower body resulting from CRPS may be eligible to participate. If eligible, patients will have a baseline visit followed by a trial of the device. If the trial is successful, defined as $\geq 50\%$ pain relief of with the system across 3-12 days, the permanent system will be implanted. Patients will return to the clinic at 1, 3, 6 and 12 months for follow-up. The primary outcome measure is the rate of serious adverse events during the study. Secondary outcome measures are pain intensity, physical function, and global health state. Additional measures include signs and symptoms of CRPS, sleep disturbance, and patient global impression of change.