SEP 17, 2024

Medtronic pioneering ADAPT-PD clinical trial methods manuscript published, setting new standards in Parkinson's disease research

ADAPT-PD trial methods and preliminary data published in npj Parkinson's disease

Medtronic plc, a global leader in healthcare technology, today announced its novel approach to studying adaptive deep brain stimulation (aDBS) was published in *npj Parkinson's Disease*, which is part of the prestigious Nature Portfolio of journals.

The Adaptive DBS Algorithm for Personalized Therapy in Parkinson's Disease (ADAPT-PD) trial is a global, multi-center, prospective, single-blind, and randomized crossover study developed to evaluate the safety and effectiveness of chronic dual and single threshold aDBS modes (as compared to continuous DBS) across all Parkinson's disease (PD) patients eligible for DBS. The study is currently ongoing and will be the largest and longest assessment of aDBS in an 'at-home' setting.

The publication describes the clinical trial design, objectives, programming steps, and preliminary data on the enrolled cohort. The clinical trial has enrolled 68 participants with either subthalamic nucleus or globus pallidus internus DBS connected to a Percept™ PC neurostimulator. The preliminary data from the screening and enrollment phase indicate a high brain signal presence both on and off medications, in both DBS target locations and in patients of all PD phenotypes. This information is foundational for the real-world application of aDBS for patients. The final results of the trial will be the longest assessment of at-home aDBS and the first to assess aDBS in patients with subthalamic nucleus or globus pallidus internus DBS. An additional supplementary directional aDBS cohort will garner the first ever clinical evaluation of directional aDBS.

"This groundbreaking trial is led by our exceptional Medtronic Brain Modulation research, development and clinical teams in close partnership with more than a dozen world renowned Neurologists and Neurosurgeons from globally recognized academic institutions," said Scott Stanslaski, lead Methods manuscript author and Senior Distinguished Engineer, Medtronic Brain Modulation within the Neuromodulation business, which is part of the Neuroscience Portfolio. "This clinical trial and associated methodology, represents a significant advancement in our understanding of aDBS therapy for Parkinson's disease."

The trial included a cohort of 68 patients with a sensing-enabled Medtronic Percept™ PC neurostimulator. Trial

participants were monitored over four phases spanning more than a year, including baseline examination, initial aDBS set up and adjustment, evaluation, and long-term follow-up. Participants were then offered extended access to aDBS therapy after the long-term follow-up period.

Medtronic recently filed for U.S. FDA approval of aDBS; it is not yet approved for sale or distribution. The results of the ADAPT-PD trial are expected to support the global regulatory submissions to commercialize aDBS for people living with PD.

"For more than three decades, Medtronic's investment in DBS research has led to significant improvements in therapeutic treatment for movement disorders and epilepsy," said Amaza Reitmeier, vice president and general manager, Medtronic Brain Modulation. "This first-of-its-kind trial is a significant step forward in our journey to bring sensing-enabled DBS enhancements to patients."The Medtronic Percept™ family of neurostimulators with exclusive BrainSense™ technology is the first and only DBS system with sensing, directionality, and advanced programming.[1]

BrainSense™ technology uses brain signals to provide insights into a patient's condition, in real time, over time.[1]

For more than 30 years, Medtronic has served over 180 thousand people with movement disorders and other indications in more than 70 countries with its life-changing DBS therapy[1].

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow Medtronic on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

Medtronic DBS therapy is approved for five indications: Parkinson's disease, essential tremor, dystonia*, obsessive-compulsive disorder* (OCD), and epilepsy. Indications vary by product. Refer to product labeling for details.

*Humanitarian device: The effectiveness of these devices for the treatment of dystonia and obsessive-compulsive disorder has not been demonstrated.

References

1. Medtronic data on file.

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https://news.medtronic.com/Medtronic-pioneering-ADAPT-PD-clinical-trial-methods-manuscript-published,-setting-new-standards-in-Parkinsons-disease-research