The NeuRx® Diaphragm Pacing System™ (DPS) has been approved for use by the United States Food and Drug Administration (FDA). But is it actually effective in prolonging survival and improving quality of life?

That’s the question being posed in a new clinical trial now beginning to enroll ALS patients at 20 centers across the United States. The study’s co-leader is Kirsten Guis, M.D., of SUNY Upstate Medical University in Syracuse, New York, explained the rationale and details of the trial in a recent webinar hosted by The ALS Association.

The diaphragm sits at the bottom of the chest cavity and is the main muscle responsible for breathing. Since respiratory failure is the most common cause of death in ALS, “treatments that improve diaphragm function are likely to improve ALS patient survival,” Dr. Guis said.

That’s the idea behind the DPS. By delivering direct electrical stimulation to the diaphragm, the device is intended to replace the activity of failing motor neurons that usually drive contraction of the diaphragm.

The device, developed by Synapse Biomedical, Inc., consists of electrodes surgically implanted into the diaphragm, which are connected by wires to an external “pulse generator” that delivers the stimulation. The device was approved for use by the FDA in 2011 as a “humanitarian use device,” an approval that required evidence that it did not pose “an unreasonable or significant risk of illness or injury and that the probable benefit to health outweighs the risk of injury or illness from its use.”

The purpose of the new clinical trial is to further confirm initial findings and determine whether DPS extends survival in patients and provides improved quality of life in comparison to other current clinical management practices.

The trial will enroll 180 ALS patients who have not yet begun using BiPAP (non-invasive breathing assistance) during waking hours (use at night or during naps is acceptable). Patients will be randomly assigned to one of two groups: two-thirds will undergo implantation of the DPS, and one-third will continue their regular care (called “best medical management”). Implantation of the DPS requires hospital admission and general anesthesia. The electrodes are inserted through a small incision in the abdominal wall. The incision is stitched closed, around the wires that connect the electrodes to the external pulse generator.
Patients in both groups will be followed regularly for 18 months. The goal of the study is to determine if use of the DPS increases survival, improves diaphragm function, and/or improves quality of life.

Dr. Guis noted that those enrolling in the trial should not necessarily expect to benefit from treatment, since the reason for the trial is to determine whether the DPS provides any benefit. But, she pointed out, study participants, including those who do not receive the DPS, “may still receive benefit from study participation, as they will undergo intensive testing for breathing muscle weakness. This testing may result in earlier detection and treatment of breathing symptoms.”

Information about enrollment will be available in the near future.