

Michigan Health Systems

Progress made in stem cell clinical trial involving Eva Feldman, M.D.

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Researchers including U-M's Eva Feldman, M.D., Ph.D, have received approval from the Food and Drug Administration (FDA) to advance to the next phase of a landmark trial to treat patients with Amyotrophic Lateral Sclerosis (ALS) using human neural stem cells.

The Phase I trial, currently underway exclusively at Emory University, is designed to assess the safety of implanting neural stem cells into the spinal cord in up to 18 people with ALS and began in January 2010. The first 12 patients received neural stem cell transplants in the lumbar, or lower, region of the spinal cord. After reviewing safety data from these patients, the FDA has granted approval for the trial to advance to the final two groups of patients (three in each group), all of who will be transplanted in the cervical, or upper, region of the spinal cord.

Also known as Lou Gehrig's disease, ALS is a fatal neurodegenerative disease with no known cure. It causes the deterioration of specific nerve cells in the brain and spinal cord called motor neurons, which control muscle movement. As the illness progresses, patients lose their ability to walk, talk and breathe. According to the ALS Association, approximately 30,000 Americans have ALS at any given time and patients with the disease usually die within two to five years of diagnosis.

This is the first U.S. clinical trial of stem cell injections into the spinal cord for the treatment of ALS.

The study, in collaboration with the University of Michigan, is funded by the Maryland-based biotech company, Neuralstem, Inc., which is also providing the human neural stem cells for transplantation.

Feldman is director of the A. Alfred Taubman Medical Research Institute and a professor of Neurology at U-M. She also is president of the American Neurological Association.