

NEWS

IMAGINE

Trials show promise for patients with spinal cord injuries

By **MaryLynn Schiavi**

Special to the Home News Tribune

This monthly column explores ideas, insights and discoveries made in New Jersey that are shaping our future.

The body has extraordinary self-healing capabilities, and one New Jersey researcher is building on nature's regenerative powers with the development of a new delivery system designed to increase the effectiveness and safety of stem cell therapy for spinal cord injuries and other regenerative medicine applications.

The StemCell Bag™ is a new method for reintroducing healthy adult stem cells into the body to regenerate spinal nerves in patients with spinal cord injuries often caused by severe traumas from car accidents and sports injuries.

Using adult stem cells that are derived from the patient's own body, as opposed to the more controversial embryonic stem cells, which are developed in vitro, Dr. Hatem Sabaawy, founder of Celvive, is delighted with the results of clinical trials conducted on patients in an international study.

"The outcome has been amazing. Many of the patients were confined to their beds and wheelchairs, unable to walk. As a result of the treatment, one out of two patients regained sensation and improved motor improvement and were able to regain mobility," said Sabaawy, an assistant professor of medicine in the medical oncology division at UMDNJ-Robert Wood Johnson Medical School and the Cancer Institute of New Jersey in New Brunswick.

He said the overall response rate was that 23 out of 50 patients, or 46 percent, showed neurological improvements, and many of the 23 patients were able to walk with canes.



Dr. Hatem Sabaawy

Sabaawy said the first phase of the trial was not designed to produce motor gain enabling patients to walk, but rather to test the safety of cell therapy; therefore, a fixed cell dose was given to all 50 patients that had different injuries. The next trial will involve a dose escalation study and will evaluate motor responses and walking, he said.

Harnessing power of adult stem cells

The challenge to utilizing adult stem cells has been the threat of contamination of the cells between the time they are withdrawn from the body and then reintroduced.

The new technology makes it possible to deliver bone marrow cells from the hips of spinal cord-injury patients directly to the patient's injury site by passing them through the StemCell Bag, which is a sealed multiple-bag device.

Sabaawy explained that the material of the bag is similar to material currently used in blood bags and does not interact with human cells.

"What we've done is to create a closed system to minimize the introduction of pathogens so the cells are not exposed to outside chemicals or agents," said Reza Razavi, acting chief scientific officer and interim chief executive officer of Celvive, a Delaware-based company with offices in New Brunswick.

Razavi is also director of New Ventures and Strategic Initiatives at Foundation Venture Capital Group, based in New Brunswick. Celvive has secured a pre-seed investment of up to \$500,000 from FVCG to further develop its technology.

Based on the promising results from the Cairo University study, Sabaawy is expecting to move forward with clinical trials in the United States within two years.

Adult vs. embryonic stem cells

According to Sabaawy and Razavi, using adult stem cells as opposed to embryonic is preferable for a number of reasons. In addition to the ethical and moral debate over the use of embryonic cells, their strength is also their weakness. "Because embryonic stem cells can differentiate into all types of tissue, they can also grow tumors," Sabaawy said.

He said a great deal of research is still needed to determine how to safely use embryonic stem cells, but currently there is no evidence that adult stem cells produce tumors if they have not been manipulated or contaminated in some way.

He also said there are virtually no side effects involved in the outpatient procedure other than temporary pain or swelling at the injection site and/or a headache. To read the results of the study, visit <http://bit.ly/15tIFRp>.