

Northwestern Medicine researchers investigate stem cell therapy for stroke

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Each year, nearly 800,000 Americans suffer a stroke which can result in permanent brain damage, long term disability or death. As a leading cause of adult disability, stroke has an annual burden of more than \$62 billion on the United States economy. With the exception of rehabilitation therapy, very few treatments are available to improve the chronic neurologic deficits caused by a stroke. In hopes of expanding therapeutic options, Northwestern Medicine researchers are investigating a novel stem cell therapy, known as SB623, that may hold the key to improving motor function following a disabling stroke.

Northwestern is currently one of only three sites in the nation enrolling participants in a landmark study to test the safety and efficacy of adult stem cell therapy for patients with stable ischemic stroke. Accounting for 87 percent of strokes, ischemic stroke occurs when a blocked artery interrupts the flow of oxygen and blood to the brain. This causes cell death and brain damage which can leave a person with impaired body functions, including paralysis, weakness on one side, difficulty with speech and language, vision issues, and cognitive challenges.

"Two million <u>brain cells</u> die each minute during a stroke making it critical to get treatment fast at the earliest sign of symptoms; once brain damage occurs, there's very little that can be done medically to reverse it," said principal investigator Joshua Rosenow, MD, director of Functional Neurosurgery at Northwestern Memorial Hospital and associate professor of neurosurgery, neurology, and physical medicine and rehabilitation at Northwestern University Feinberg School of



Medicine. "While this study is only a preliminary step towards understanding the healing potential of these cells, we are excited about what a successful trial could do for a patient population that currently has very limited therapeutic options."

While the study's primary purpose is to examine the safety of SB623 stem cells, researchers will also seek to determine if the cells are effective in improving stroke symptoms. SB623 is derived from genetically engineered adult bone marrow cells from a healthy adult donor.

"Although not proven in humans, these stem cells have been shown to promote healing and improve function when administered in animal models of stable stroke," said co-investigator Richard Bernstein, MD, director of Northwestern Memorial's Stroke Center and associate professor of neurology at the Feinberg School. "The cells did not replace the neurons destroyed by stroke, but instead they appeared to encourage the brain to heal itself and promote the body's natural regenerative process. Eventually, the implanted stem cells disappeared."

"In this study, the cells are transplanted into the brain using brain mapping technology and scans, allowing us to precisely deposit the cells in the brain adjacent to the area damaged by stroke," explained Rosenow.

Early participants have received 2.5 million cells, but as the study progresses the dose will escalate to 5 million and eventually 10 million cells. Since SB623 cells are allogeneic, a single donor's cells can be used to treat many other individuals. Participants in the study will be followed for up to two years with periodic evaluations for safety and effectiveness in the improvement in motor function.

"Stroke can be a very disabling and life changing event," said Bernstein.



"Even just a slight improvement in function could make a huge difference for a person impacted by stroke. To potentially give our patients the opportunity to permanently regain movement or speech is a very exciting prospect. In the animal models, the improvements appeared to remain even after the implanted stem cells disappeared."

Even at this early phase, researchers recognize the promise that stem cell therapy may hold. "If these <u>cells</u> are proven effective in improving, or even reversing brain damage, the implications of a successful outcome reach far beyond just stroke," said Rosenow. "Stem cell therapy may hold the key to treating a wide range of neurological disorders that currently do not have many available therapies. The Northwestern team is very excited to be a part of this groundbreaking trial."

More information: To be considered for the trial, participants must be 18 to 75 and have had an ischemic stroke in the last six to 36 months. They should have moderate to severe symptoms with impaired motor function. Full inclusion and exclusion criteria are available online. The FDA-approved phase 1-11 study is expected to enroll 18 participants nationwide and last up to two years. Patients may complete an online questionnaire to help determine their eligibility at stemcellstudy.ucsf.edu/index.php

Provided by Northwestern Memorial Hospital

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