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First Successful Clinical Trial to Protect the Brain from Damage Caused by Stroke

A team of Canadian scientists and clinicians, led by Dr. Michael Hill of the Calgary Stroke Program at Foothills Medical Centre and University of Calgary's Hotchkiss Brain Institute (HBI), have demonstrated that a neuroprotectant drug, developed by Dr. Michael Tymianski at the Krembil Neuroscience Centre, located at the Toronto Western Hospital, protects the human brain against the damaging effects of stroke.

The study, "Safety and efficacy of NA-1 for neuroprotection in iatrogenic stroke after endovascular aneurysm repair: a randomized controlled trial," published online October 8 in The Lancet Neurology, was conducted concurrently with a laboratory study published in Science Translational Medicine, that predicted the benefits of the stroke drug.

This landmark clinical trial was a randomized, double blinded, multi-centre trial that was conducted in Canada and the USA. The study evaluated the effectiveness of NA-1[Tat-NR2B9c] when it was administered after the onset of small strokes that are incurred by patients who undergo neurointerventional procedures to repair brain aneurysms. This type of small ischemic stroke occurs in over 90% of aneurysm patients after such a procedure, but usually does not cause overt neurological disability.

In the clinical trial, patients were randomized to receive either Tat-NR2B9c or placebo. Those treated with Tat-NR2B9c showed a reduction in the amount of brain damage sustained as a result of the aneurysm repair procedure. Also, in patients who had ruptured brain aneurysm, which comprise a population of patients at very high risk of neurological damage, those treated with Tat-NR2B9c all had good neurological outcomes, whereas only 68% of those treated with placebo had good outcomes.

"The results of this clinical trial represent a major leap forward for stroke research," said Dr. Hill. "There have been over 1,000 attempts to develop such drugs, which have failed to make the leap between success in the lab and in humans."

"This clinical trial is, to our knowledge, the first time that a drug aimed at increasing the resistance of the brain to stroke, has been shown to reduce stroke damage in humans. No efforts should be spared to develop it further," said Dr. Michael Tymianski, who oversaw the development of Tat-NR2B9c from its invention in his lab, through to clinical trials.

Currently, t-PA is the only widely approved acute stroke therapy. It works by unblocking the arteries to the brain, however, this treatment is only beneficial for a portion of stroke victims. It also has serious potential for side-effects, including bleeding in the brain.

"Through our lab research and clinical trial, we now have a better method of predicting whether a stroke drug may be effective in humans and we now have the evidence that there is a neuroprotectant that can prevent damage in the brain caused by reduced blood flow," said Dr. Tymianski, inventor of NA-1 and one of the study's authors. "The benefits of this can be explored not only for stroke, but for other conditions such as vascular dementia."

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