



INTERDISCIPLINARY STEM CELL INSTITUTE

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## NEW STUDY FINDS STEM CELL THERAPY VIA INTRA-CAROTID ARTERY INFUSION SAFE FOR TREATMENT OF STROKE

**FIRST-EVER RANDOMIZED CONTROLLED STUDY LED BY UNIVERSITY OF MIAMI PHYSICIAN-SCIENTISTS FINDS THAT STEM CELL THERAPY VIA INTRA-CAROTID ARTERY IS A SAFE AND VIABLE OPTION FOR THE TREATMENT OF ISCHEMIC STROKE**

**Miami, FL– April 23, 2015** – A yearlong study of patients who had suffered from ischemic strokes, led by physician-scientists at the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine, has found that stem cells can be safely infused to the brain through the carotid artery within two weeks after a stroke. The national co-principal investigator of the study, Dr. Dileep Yavagal, presented the discovery abstract of the RECOVER-Stroke trial entitled *Intra-Arterial Delivery of Autologous Aldhbr Cells in Ischemic Stroke: Final 1-Year Results of the Recover-Stroke Trial* at the European Stroke Organization Conference, in the UK. The significance of the findings provides new hope for future stroke treatments as well as for other brain-related illnesses.

“We are excited by the findings of the new study as it offers promise for stroke victims and for those with other neurological conditions,” says Dr. Yavagal, Director of Interventional Neurology, Co-Director of Endovascular Neurology, Associate Professor of Neurology and Neurosurgery at the University of Miami Miller School of Medicine and faculty member at the Interdisciplinary Stem Cell Institute. “Previous thought was that stem cell use for brain conditions could lead to worsening stroke or even brain cancer. The conclusions of our research prove that stem cells are safe when given through the carotid artery with a small catheter to treat neurological illnesses and we can continue to explore the efficacy of stem cells for treatments.”

After a full year of stem cell injections, no increased serious adverse effects were detected in any patients. Specifically, no ischemia related neurologic worsening was seen as a result of the intra-carotid infusion of stem cells. The intra-arterial approach for cell delivery is worth pursuing for cell-based stroke therapy in future larger studies.

“We are extremely proud to be able to impact the direction of stem cell research with studies like RECOVER-stroke,” says Dr. Joshua M. Hare, Founding Director of the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine. “We look forward to both witnessing and acting as a key player in the medical innovations that result from these findings.”

The University of Miami was the only east coast institute to participate in the nationwide multi-center RECOVER-Stroke trial that led to the discovery. The study was sponsored by clinical-stage biopharmaceutical company, Aldagen, which has since been acquired by Nuo Therapeutics, Inc. The goal of the trial was to assess the safety and preliminary efficacy of intra-arterial delivery of stem cells. The University of Miami recruited the second highest number patients in the trial. In total, 48 patients participated in the study: 19 received the placebo and 29 received IA ALDHbr cells, which were manufactured by Aldagen. All patients in the double-blind study received stem cells intra-arterially 13-19 days post-stroke. At 24 hours patients were assessed for clinical worsening and at one year for serious adverse effects and radiological worsening. Efficacy on multiple functional disability scales were evaluated at 90, 180 and 365 days.

“This study opens the door to future clinical trials that will explore new methods of repairing damage to the brain with cell-based therapies,” says Dr. Ralph L. Sacco, Chairman of Neurology at the University of Miami Miller School of Medicine and Chief of Neurology Services at Jackson Memorial Hospital. “Stroke researchers now know that stem cells can be used safely, and efficiently without compromising the health of the patient. We have more work to do in this promising area to improve the outcomes of our stroke patients.”

While stem cell research continues to prove to be a viable form a therapy in other areas, doctors hope to have the same success in finding new stem cell therapies for the treatments of neurological illnesses. Dr. Yavagal continues to study new strategies to improve the delivery of stem cells via catheter into the carotid artery for treatment of stroke. He has received funding for his research from the NIH CTSI, Florida Biomedical Agency, and the Anderson Family.

### **About Interdisciplinary Stem Cell Institute**

The Interdisciplinary Stem Cell Institute (ISCI), founded in 2008 at the University Of Miami Miller School of Medicine, is on the cutting-edge of translating stem cell therapies. ISCI's goal is to spearhead cell-based therapies for a host of untreatable diseases. Its focus includes research in basic cell biology, hematology, oncology, cardiology, dermatology, diabetes and endocrinology, neurology, orthopaedics, pediatrics, and ethics and science policy. ISCI's physician-scientists are dedicated to rapidly applying knowledge of stem cell biology to advance therapies for hard-to-treat diseases in an ethical and rigorous manner.

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