

MindRhythm Initiates Pivotal Portion of Prehospital Stroke Trial

CUPERTINO, CALIFORNIA, UNITED STATES, February 14, 2023 /EINPresswire.com/ -- [MindRhythm](#) Inc, in partnership with Wayne State University School of Medicine in Detroit, Michigan, today announces the conclusion of phase I and initiation of the pivotal portion of its hEadPulse for Ischemic StrOke DEtection Prehospital Study (EPISODE-VS).

The EPISODE trial is designed to evaluate the use of MindRhythm's proprietary Harmony[®] headset technology for identifying large vessel occlusion (LVO) ischemic strokes in the prehospital setting. In previous studies, cranial accelerometry, the primary technology used in the Harmony[®] headset, has been shown to reliably detect LVO in hospitalized patients suspected of experiencing an ischemic stroke. MindRhythm's technology may be especially appealing to medical providers as it allows noninvasive measurement of a physiological parameter MindRhythm calls the HeadPulse[®]. Whereas previous studies assessed patients in the hospital, the EPISODE trial is designed to validate device performance in the prehospital environment.

Thanks to the contributions of MindRhythm's partners in research, EPISODE is one of the largest prehospital medical device trials in stroke ever conducted. The pivotal portion of the trial is expected to replicate the results of the observational phase in a blinded fashion.

The study's Principal Investigator, Dr. James H. Paxton, MD, Emergency Physician, Associate Professor, Director of Clinical Research at Detroit Receiving Hospital / Wayne State University School of Medicine, in Detroit, Michigan stated, "We're encouraged by the early results, and are excited to verify our findings in the pivotal portion of the trial. The use of a noninvasive device like the Harmony[®] headset has the potential to revolutionize prehospital care as an invaluable tool for detecting LVO strokes earlier, potentially improving outcomes for patients suffering from the worst kinds of stroke."

Jeffrey L. Saver, MD, FAHA, FAAN, FANA, Professor and SA Vice Chair for Clinical Research Carol and James Collins Chair, Department of Neurology
Director, UCLA Comprehensive Stroke and Vascular Neurology Program
and developer of the standard of care stroke detection tool: the Los Angeles Motor Scale stated "The ability to identify and triage stroke patients directly to a hospital that can provide the most appropriate level of care shortens time to treatment for this devastating disease. This technology could have a substantial benefit for acute stroke care."

The results from phase I are promising, suggesting that the Harmony[®] headset may detect LVO with a level of accuracy that is non-inferior to the Los Angeles Motor Scale (LAMS) stroke scoring tool. This preliminary and additional validation data will support MindRhythm's upcoming FDA submission of its innovative stroke detection tool.

MindRhythm, Inc., was founded by John Keane, Dr. Wade Smith MD, PhD, and Dr. Paul Lovoi, PhD, in 2019 as a brain wellness company. The company's initial focus is on optimizing stroke triage in the prehospital setting. MindRhythm's Harmony device is a novel, non-invasive, diagnostic that is able to identify a variety of neurological conditions such as stroke and concussion by monitoring a specific waveform in the brain discovered by MindRhythm. In stroke, the intent is to optimize time to treatment by accurately identifying LVO ischemic stroke in the prehospital environment. To learn more about MindRhythm and the Harmony[®] headset, visit <https://mindrhythm.com>

ABOUT MINDRHYTHM

MindRhythm is a medical technology company focused on preventing neurological injury. Founded by world-renowned scientific experts with significant commercialization success, MindRhythm's monitoring technology provides real-time visibility to life-threatening situations at home, prehospital, in the operating room, and on the field. MindRhythm's technology allows clinicians to intervene, optimize and manage care to prevent brain damage. Collaborating with the healthcare community, MindRhythm looks to apply a systematic approach to reducing time to treatment in strokes and monitor neurological health during recovery from injury. Together, let's save lives and improve the quality of life: <https://mindrhythm.com>

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