ICU
MANAGEMENT & PRACTICE

Velomedix Commences Rapid Therapeutic Hypothermia System Pilot Study in Heart Attack

Velomedix, a venture-backed medical device company advancing the field of therapeutic hypothermia, announced the enrollment of the first patient in its VELOCITY pilot study. VELOCITY is a prospective, randomized, multi-center study designed to further evaluate the safety and feasibility of the Velomedix rapid therapeutic hypothermia system in patients with acute myocardial infarction (AMIs or heart attacks). The first patient was enrolled by David Shavelle, M.D., at the University Of Southern California Keck School Of Medicine in Los Angeles, CA.

The VELOCITY study will enroll 60 awake patients with ST segment elevation myocardial infarctions (STEMIs) at multiple U.S. and Canadian sites. Patients will be randomized to either primary percutaneous coronary intervention (PCI) or a combination of primary PCI and cooling to therapeutic temperatures before reperfusion.

"The case went very well, with no delay in door-to-balloon time," said Dr. Shavelle. "Any concerns we had with the peritoneal access are essentially gone and the patient has been doing well since his treatment. If this technology shows the expected benefit for these STEMI patients, I could see it become the standard of care for these patients."

The study's primary endpoint is a composite of specific new-onset, serious adverse events during the first thirty days following treatment. Several secondary endpoints will also be collected, including infarct size, myocardial salvage, left ventricular volumes, and left ventricular ejection fraction, assessed by cardiac magnetic resonance imaging (MRI). The study will thus gather initial efficacy information in addition to primary safety data.

Previous studies of therapeutic hypothermia in AMI patients have shown that cooling can significantly reduce the severity of STEMIs only if patients are cooled to temperatures of less than 35°C prior to PCI. The Velomedix approach may be unique in its ability to cool patients to this desired temperature in less than 15 minutes.

"Over the past ten years, we have seen several failed attempts to leverage therapeutic hypothermia to improve AMI patient outcomes. We now realize that a technology must be able to cool a patient to below 35°C without extending door-to-balloon times in order to be effective and adopted into today's time-sensitive AMI treatment workflows," said Gregg Stone, M.D., Columbia University Medical Center / New York-Presbyterian Hospital and co-principal investigator of the VELOCITY trial. "Velomedix appears to have developed an ultrafast cooling technology that might be effective without significantly delaying reperfusion."

Source: Velomedix

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