

News from Life Recovery Systems

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Life Recovery Systems Receives NIH Grant To Study Expanded Use of Its ThermoSuit System

Study Will Investigate Using Cooling Device to Treat Heart Attack Victims

WALDWICK, NJ, Oct. 20 -- Life Recovery Systems has received a competitively awarded \$700,000 grant from the National Institutes of Health (NIH) to conduct a clinical study to investigate the feasibility of cooling heart attack patients with its ThermoSuit® System, the only cooling device using cold water immersion to rapidly lower patient temperature.

The grant was awarded through the Small Business Innovation Research (SBIR) program of the National Heart, Lung and Blood Institute (NHLBI) of NIH. This is the third SBIR grant for Live Recovery Systems from NHLBI. The two previous grants totaling \$1.3 million were to develop the ThermoSuit System.

Twenty patients will be enrolled in the study, which will be conducted under an Investigational Device Exemption that was previously granted to Life Recovery Systems by the Food and Drug Administration. The study is a cooperative effort between Life Recovery Systems and the Ochsner Heart and Vascular Institute in New Orleans, a division of Ochsner Health System, a non-profit academic and healthcare delivery system with seven hospitals and more than 35 health centers in Southeast Louisiana.

The trial will explore the feasibility of cooling heart attack (ST-elevation acute myocardial infarction) patients with the ThermoSuit System before blood flow is restored to the heart. Patients will be sedated and cooled after entry into the emergency room and prior to percutaneous coronary intervention in the catheterization laboratory. It is expected that the ThermoSuit System will enable cooling of the patient to 34°C after a

treatment of 30 minutes or less and within the 90-minute door to balloon time requirement for treating ST-elevation acute myocardial infarction patients.

A successful result of the study will lead to a pivotal clinical study to investigate the potential for the ThermoSuit cooling treatment to reduce the severity of the heart attack. Previous research has suggested that cooling of some types of heart attack patients before coronary reperfusion could result in a significant reduction in the amount of injury the heart suffers.

The ultimate goal of these studies is to obtain FDA clearance for the use of the ThermoSuit System in treating heart attack patients. Life Recovery Systems believes that this would contribute to better outcomes for such patients and thus substantially increase the potential uses and market for its unique cooling technology.

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