

News from Life Recovery Systems

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FDA Approves Testing to Explore Effectiveness of Rapid Patient Cooling in Traumatic Brain Injury Cases

Results of ThermoSuit® System Study Could Benefit Brain Injury Casualties of Iraq War

WALDWICK, NJ, Sept. 9, 2008 - Life Recovery Systems' ThermoSuit® System, a rapid patient cooling device, has been approved by the U.S. Food and Drug Administration for use in a clinical study of patients with traumatic brain injury. Currently, the ThermoSuit System is used to induce rapid cooling of victims of cardiac arrest and heart attacks.

The study is being conducted under an Investigational Device Exemption by Dr. Guy Clifton and other researchers at the University of Texas Health Science Center in Houston, whose Institutional Review Board has also approved the study.

The study will explore whether the induction of hypothermia to 35°C in two-and-a-half hours after severe traumatic brain injury and reaching 33°C by four hours after injury and maintained for 48 hours in patients aged 16-45 will result in an increased number of patients with good outcomes at six months and 12 months after injury compared to patients randomized to normothermia. Previous research conducted by the Houston-based researchers indicated that later cooling was ineffective in reducing brain injury. The researchers concluded that more rapid cooling methods are needed to achieve a benefit in these patients.

“If the study proves to be successful, the ThermoSuit System could potentially benefit thousands of patients with traumatic brain injury,” said Milton Frank, Life Recovery Systems' COO. “Traumatic brain injury is the ‘signature wound’ of the Iraq war, and LRS is hopeful that early cooling will be beneficial to a number of military casualties.”

The ThermoSuit System, a non-invasive cooling technology was adopted for the current study because of its rapid cooling capabilities, safety and ease of use in an emergency department. While other non-invasive cooling methods typically require hours to cool the patient to the target temperatures of this protocol, the ThermoSuit System is able to provide the desired amount of cooling in less than 30 minutes.

The 240-patient study titled, “National Acute Brain Injury Study: Hypothermia IIR” (NABIS:HIIR), is being sponsored by the National Institute of Neurological Disorders and Stroke (NINDS). The study currently includes five participating hospitals in addition to the University of Texas.

Life Recovery Systems developed and markets the ThermoSuit® System, the fastest noninvasive hypothermia device. The first products were shipped in February 2007. The system continuously pumps a thin film of ice water around the patient’s body until the temperature reaches a preset level. This unique technology cools patients at a rate of one degree centigrade for every seven minutes of treatment. The duration of cooling treatment required to achieve the target temperature is typically 20 to 30 minutes. Numerous publications support the potential benefits of rapid cooling. After cooling, the patient is removed from the ThermoSuit System and can easily be transported around the hospital for other therapeutic treatments. Patients cooled with the ThermoSuit System typically stay cold for hours with little or no further maintenance cooling required.

For additional information about the NABIS:HIIR study, please go to <http://clinicaltrials.gov/ct2/show/NCT00178711?cond=%22Hypothermia%22&rank=22>

For additional information about Life Recovery Systems and the ThermoSuit System, go to <http://www.life-recovery.com/>.

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Note to Editors: Photos of the ThermoSuit System are available.