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HBN-1 Regulated Hypothermia Formulation and Evaluation of Toxicity

More than 325,000 cardiac arrests occur each year in the United States. A cardiac arrest, when the heart suddenly stops beating, causes loss of consciousness and death if untreated after several minutes. Patients who are revived from cardiac arrest can suffer from brain injury due to lack of blood flow to the brain during the event.

Therapeutic hypothermia, in which a patient's body temperature is lowered, can help prevent brain injury after cardiac arrest. Currently, health care providers lower body temperature with a combination of ice bags, cooling pads and drugs. However, less than 12 percent of hospitals use therapeutic hypothermia because it is complex, it can take too much time and the drugs can be dangerous. This project's investigators will develop a drug called HBN-1 that causes hypothermia by affecting the brain region that controls body temperature. This new approach would allow paramedics to inject the drug intravenously (through an IV) to more quickly and safely induce therapeutic hypothermia.

Scientific Synopsis

Patients resuscitated from cardiac arrest often suffer devastating brain damage. Therapeutic hypothermia dramatically improves survival with good neurological outcomes in more than half of patients who remain comatose after cardiac arrest. Given this evidence, the American Heart Association and International Liaison Committee on Resuscitation (ILCOR) incorporated therapeutic hypothermia into their 2010 treatment guidelines. To lower body temperature, medical personnel currently use mechanical methods, including ice bags, cooling pads and endovascular devices to forcefully lower body temperature. Used alone, these methods cannot completely induce hypothermia because of the body's ability to tightly thermoregulate with shivering, vasoconstriction and increased metabolism. As a result, potentially dangerous agents such as narcotics and paralyzing drugs must be given to enhance the cooling process. Less than 12 percent of hospitals use therapeutic hypothermia because the current cooling methods are considered complex and potentially dangerous.

The investigators developed HBN-1 as a simple and effective alternative to forced cooling to induce therapeutic hypothermia. HBN-1 induces regulated therapeutic hypothermia and neuroprotection. Regulated hypothermia is a drug-induced lowering of

the body's temperature set point in the hypothalamus. When the set point is lowered, the body lowers metabolism, blocks shivering and increases heat loss through peripheral vasodilatation and sweating.

HBN-1 is a patented pharmaceutical preparation that induces rapid and prolonged regulated hypothermia at room temperature without paralysis, sedation, ancillary equipment or need for mechanical ventilation. The formulation is administered intravenously so paramedics can give it in the field to minimize delays in inducing therapeutic hypothermia. HBN-1 provides a new approach for inducing and maintaining therapeutic hypothermia and overcoming the current barriers to its use in hospitals.

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