



National Heart, Lung, and Blood  
Institute

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### **NHLBI launches body cooling treatment study for pediatric cardiac arrest**

*NIH funds first large-scale, multicenter study to explore the use of temperature regulation in infants and children after cardiac arrest*

The National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health, has launched the first large-scale, multicenter study to investigate the effectiveness of body cooling treatment in infants and children who have had cardiac arrest. The Therapeutic Hypothermia after Pediatric Cardiac Arrest (THAPCA) trials total more than \$21 million over six years.

Therapeutic hypothermia, or body cooling, has been successfully used in adults after cardiac arrest and in newborn infants after birth asphyxia, or lack of oxygen, to improve survival and outcomes, but it has not been studied in infants or children who have had cardiac arrest.

“Children who have experienced cardiac arrest can suffer long-term neurological damage or death,” said NHLBI Acting Director Susan B. Shurin, M.D., a board-certified pediatrician. “There are abundant data demonstrating the benefits of hypothermia in adults with cardiac arrest, but very limited experience in children. This study begins to assess the effectiveness of therapeutic hypothermia in children, and should lead to evidence-based guidelines that will optimize both quality and rates of survival.”

During body cooling treatment, THAPCA participants lie on mattresses and are covered with blankets. Machines circulate water through the blankets and mattresses to control the participants’ body temperatures. Researchers do not yet know how body cooling will affect participants, since many factors can contribute to brain injury after cardiac arrest. However, they believe body cooling could provide several benefits, including less inflammation and cell death.

According to a 2008 review of pediatric cardiopulmonary resuscitation in the journal *Pediatrics*, about 16,000 children suffer cardiac arrest each year in the United States.

Their hearts stop pumping effectively, and blood stops flowing to their brains and other vital organs. In many cases, the outcome is death or long-term disability.

Cardiac arrest in infants and children has many causes, such as strangulation, drowning, or trauma. It can also be a complication of many medical conditions.

“Our goal is to minimize brain injury in infants and children who experience cardiac arrest and ultimately improve survival rates,” said co-principal investigator J. Michael Dean, M.D., M.B.A., professor of pediatrics and chief of the Division of Pediatric Critical Care Medicine at the University of Utah School of Medicine, Salt Lake City.

The THAPCA centers enroll participants in one of two randomized, controlled clinical trials. One evaluates participants who suffered cardiac arrest outside the hospital, while the other evaluates participants who suffered cardiac arrest in the hospital. Within each trial, there are two active treatment groups: therapeutic hypothermia (cooling the patient to 89.6-93.2 Fahrenheit) and therapeutic normothermia (maintaining the patient at 96.8-99.5 Fahrenheit). Both trials are trying to reduce fever, which commonly occurs after cardiac arrest and can lead to more severe outcomes.

“These trials are addressing the question: What is the optimal temperature for an infant or child after cardiac arrest?” said co-principal investigator Frank W. Moler, M.D., M.S., a professor in the Department of Pediatrics and Communicable Diseases at the University of Michigan, Ann Arbor. He added that in previous studies exploring therapeutic hypothermia, the comparison or control groups did not receive therapeutic normothermia to prevent fever.

Participants in the THAPCA trials must be older than 48 hours and younger than 18 years and must be enrolled in the study within six hours of suffering cardiac arrest. Once a parent or guardian provides consent, the participant is randomly assigned to one of the two treatment groups. The therapeutic hypothermia group in each trial receives the hypothermia treatment for two days and then normothermia treatment for three days, which ensures that the body temperature is kept within a normal temperature range. The patients in the therapeutic normothermia groups receive normothermia treatment for all five days.

After the five-day period, the clinical care team will continue to provide study participants with optimal medical care. Participants will undergo neurological and behavioral testing a year after the cardiac arrest.

The THAPCA trials involve 34 clinical centers in the United States and Canada. The C.S. Mott Children’s Hospital at the University of Michigan serves as the lead clinical center, while the data coordinating center is based at the University of Utah School of Medicine.

The THAPCA trials are being conducted in partnership with the Collaborative Pediatric Critical Care Research Network, established in 2004 by the NIH's *Eunice Kennedy*

*Shriver* National Institute of Child Health and Human Development, and the Pediatric Emergency Care Applied Research Network, established in 2001 by the Health Resources and Services Administration's Maternal and Child Health Bureau.

The 34 participating clinical centers across North America are:

- Children's Hospital of Alabama, Birmingham
- Diamond Children's Medical Center, University of Arizona, Tucson
- Phoenix Children's Hospital
- Arkansas Children's Hospital, Little Rock
- Children's Hospital of Los Angeles
- Children's Hospital of Orange County, Orange, Calif.
- Loma Linda University Children's Hospital, Calif.
- Mattel Children's Hospital, University of California, Los Angeles
- UC Davis Children's Hospital, Sacramento, Calif.
- The Hospital for Sick Children, University of Toronto, Ontario
- Children's Hospital of Denver, Aurora, Colo.
- Children's National Medical Center, Washington, D.C.
- Children's Healthcare of Atlanta Pediatric Hospital
- Children's Memorial Hospital, Chicago
- Kosair Children's Hospital, Louisville, Ky.
- Johns Hopkins Children's Center, Baltimore
- Children's Hospital of Michigan, Detroit
- C.S. Mott Children's Hospital, University of Michigan, Ann Arbor
- Children's Hospitals and Clinics of Minnesota, Minneapolis
- St. Louis Children's Hospital, Washington University
- Children's Hospital of New York, Columbia University
- Golisano Children's Hospital, University of Rochester, N.Y.
- Cincinnati Children's Hospital Medical Center
- University Hospitals, Rainbow Babies and Children's Hospital, Cleveland
- Nationwide Children's Hospital, Columbus, Ohio
- Children's Hospital of Philadelphia
- Penn State Hershey Children's Hospital
- Children's Hospital of Pittsburgh
- Le Bonheur Children's Hospital/University of Tennessee Health Science Center, Memphis
- Monroe Carell Jr. Children's Hospital at Vanderbilt, Nashville, Tenn.
- Children's Medical Center of Dallas
- Primary Children's Medical Center, University of Utah, Salt Lake City
- Seattle Children's Hospital
- Children's Hospital of Wisconsin, Wauwatosa

More information about the THAPCA trials (NCT00880087 and NCT00878644) can be found at <http://clinicaltrials.gov/>.

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*The NHLBI plans, conducts, and supports research related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; and sleep disorders. The Institute also administers national health education campaigns on women and heart disease, healthy weight for children, and other topics. NHLBI press releases and other materials are available online at [www.nhlbi.nih.gov](http://www.nhlbi.nih.gov).*

*The National Institutes of Health — The Nation's Medical Research Agency — includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit [www.nih.gov](http://www.nih.gov).*



*Blanketrol mattress and blanket used for therapeutic hypothermia.*

#### Resources:

- *Therapeutic Hypothermia after Pediatric Cardiac Arrest (THAPCA) trials website:* <http://www.thapca.org/>

- ClinicalTrials.gov *THAPCA* trials resources:  
<http://clinicaltrials.gov/ct2/show/NCT00880087?term=THAPCA&rank=1>, and  
<http://clinicaltrials.gov/ct2/show/NCT00878644?term=THAPCA&rank=2>
- Cardiac Arrest:  
[http://www.nhlbi.nih.gov/health/dci/Diseases/scda/scda\\_what.html](http://www.nhlbi.nih.gov/health/dci/Diseases/scda/scda_what.html)
- Children and Clinical Studies:  
<http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>
- Collaborative Pediatric Critical Care Research Network (CPCCRN):  
<http://www.cpccrn.org/>
- Pediatric Emergency Care Applied Research Network (PECARN):  
<http://www.pecarn.org/>