NIH launches trials to evaluate CPR and drugs after sudden cardiac arrest

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The National Institutes of Health has launched two multi-site clinical trials to evaluate treatments for out-of-hospital cardiac arrest. One will compare continuous chest compressions (CCC) combined with pause-free rescue breathing to standard cardiopulmonary resuscitation (CPR), which includes a combination of chest compressions and pauses for rescue breathing. The other trial will compare treatment with the drug amiodarone, another drug called lidocaine, or neither medication (a salt-water placebo) in participants with shock-resistant ventricular fibrillation, a condition in which the heart beats chaotically instead of pumping blood.

The majority of the approximately 350,000 people who have cardiac arrest in the United States each year are assessed by emergency medical service (EMS) providers. During a cardiac arrest, the heart stops beating, and unless it is restarted within minutes, the person usually dies. Although immediate CPR can be lifesaving, more than 90 percent of people who experience a cardiac arrest outside of a hospital die before reaching a hospital or soon thereafter.

"Increasing survival rates for people who experience out-of-hospital cardiac arrest is a major public health goal," said Susan B. Shurin, M.D., acting director of the NIH's National Heart, Lung, and Blood Institute, which is the lead federal sponsor of the studies. "These new trials could provide critical insight about which resuscitation efforts are most effective for cardiac arrest."

The trials will serve a combined population of nearly 21 million people from diverse urban, suburban, and rural regions across the U.S. and Canada.

The CCC trial will compare survival-to-hospital-discharge rates for two CPR approaches delivered by paramedics and fire fighters. Persons experiencing cardiac arrest will be randomly assigned to receive continuous chest compressions, or standard CPR by emergency responders. Standard CPR, the approach recommended by the American Heart Association (AHA) for use by emergency responders, includes chest compressions with short pauses for assisted breathing. This approach has been called into question by emerging data suggesting that stopping chest compressions to provide assisted breathing interrupts overall blood flow, thereby lowering survival.

Previous studies have shown that people who suffer cardiac arrest outside of the hospital and are treated by bystanders are more likely to survive when given compressions alone, according to Graham Nichol, M.D., M.P.H., principal investigator of the CCC trial and a professor of medicine and director of the Center for Prehospital Emergency Care and medical director of the Clinical Trials Center at the University of Washington, Seattle. In 2010, AHA adopted new guidelines that recommended continuous chest compressions only for bystanders.

"The CCC trial will help to determine if continuous compressions is equal to or better than standard professional CPR when paramedics, who are better able to provide assisted breathing than bystanders, intervene," said Nichol.

Trained emergency personnel will give all participants in the CCC trial three cycles of CPR followed by heart rhythm analysis and, if needed, an electrical shock (defibrillation), applied to the chest. Half will be randomly assigned to receive continuous compressions combined with

pause-free rescue breathing and half will receive standard professional CPR.

The CCC trial will enroll up to 23,600 participants at eight major regional locations across the U.S. and Canada.

The Amiodarone, Lidocaine, or neither (Placebo) for Out-Of-Hospital Cardiac Arrest Due to Ventricular Fibrillation or Tachycardia study (ALPS) will determine whether amiodarone or lidocaine improves survival-to-hospital-discharge rates for participants with shock-resistant ventricular fibrillation. Participants will receive one or the other drug or a placebo.

About 25 percent of cardiac arrests are due to ventricular fibrillation. When shock treatment with a defibrillator fails to restore normal heart rhythm during ventricular fibrillation, medications such as amiodarone or lidocaine are often given, but their effectiveness in improving survival is unknown.

"Answering these questions is crucial and will determine the role of these drugs for patients who experience out-of-hospital cardiac arrest," said Peter Kudenchuk, M.D., principal investigator of the ALPS trial and the Seattle-King County Resuscitation Outcomes Consortium (ROC) clinical site, and professor of medicine and heart rhythm specialist at the University of Washington School of Medicine (UW Medicine).

The ALPS trial will enroll up to 3,000 participants at nine locations across the U.S. and Canada.

CCC and ALPS are part of the NIH-supported Resuscitation Outcomes Consortium (ROC), the first large-scale clinical research network in the world designed to study, improve, and standardize how EMS teams deliver very early, pre-hospital interventions to improve patient survival

after cardiac arrest or trauma. ROC has forged innovative multidisciplinary research partnerships between emergency physicians, cardiologists, EMS workers, trauma surgeons, and neurosurgeons to bring diverse perspectives to research that ultimately will lead to better clinical practice. As with all clinical trials funded by the NIH, an independent group of experts will monitor patient safety throughout both trials.

The NHLBI is the lead federal sponsor for both of the new studies, and the U.S. Army Medical Research and Materiel Command is a federal co-sponsor. Additional funding is provided by the Canadian Institutes of Health Research, the Heart and Stroke Foundation of Canada, the Defense Research and Development Canada, and the AHA.

Almost 60 fire and EMS organizations will participate in the ALPS trial, and approximately 125 EMS organizations will participate in the CCC trial.

Participating centers include:

- Alabama Resuscitation Center, University of Alabama at Birmingham
- University of California, San Diego Center for Resuscitation Science (ALPS only)
- Portland Resuscitation Outcomes Consortium, Oregon Health and Science University (ALPS only)
- Pittsburgh Resuscitation Network, University of Pittsburgh (CCC only)
- Dallas-Fort Worth Center for Resuscitation Research, University of Texas Southwestern Medical Center
- Seattle-King County Center for Resuscitation Research, University of Washington

- Milwaukee Resuscitation Network, Medical College of Wisconsin
- University of Ottawa Collaborative Regional Coordinating Centre, Ottawa Hospital Research Institute, Canada
- University of British Columbia Collaborative Regional Coordinating Centre, St. Paul's Hospital, Canada
- Rescu, Keenan Research Centre, Li Ka Shing Knowledge Institute, St. Michael's Hospital, University of Toronto, Canada

Both trials will be coordinated by the University of Washington in Seattle.

More information: Find out more about the CCC trial at clinicaltrials.gov/ct2/show/NCT01372748 and about ALPS at clinicaltrials.gov/ct2/show/NCT01401647

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