

**Protocol Registration Receipt**

2005-09-12

IND Grantor: CDRH IND Number: G050062 IND Serial Number:

**ResQ Trial: Impact of an Impedance Threshold Device and Active Compression Decompression CPR on Survival from Out-of-Hospital Cardiac Arrest**

**This study is not yet open for patient recruitment.**

Verified by Advanced Circulatory Systems 2005-09

<b>Sponsored by:</b>	Advanced Circulatory Systems
<b>Information provided by:</b>	Advanced Circulatory Systems
<b>ClinicalTrials.gov Identifier:</b>	

**► Purpose**

The purpose of this study is to determine whether performing active compression decompression cardiopulmonary resuscitation (ACD-CPR) with an impedance threshold device (ITD) or using an ITD with conventional CPR will impact the neurologic recovery and survival to hospital discharge following out-of-hospital cardiac arrest.

Condition	Treatment or Intervention	Phase
Heart Arrest Death, Sudden, Cardiac Cardiopulmonary Resuscitation	Device: ResQPOD CE CA, an impedance threshold device (ITD) Device: ResQPump, an active compression decompression CPR device	N/A

Study Type: Interventional

Study Design: Treatment, Randomized, Single Blind, Active Control, Factorial Assignment, Safety/Efficacy Study

Official Title: ResQ Trial: Comparison of Standard Cardiopulmonary Resuscitation (CPR) Alone Versus Active Compression Decompression CPR Plus an Impedance Threshold Device (ITD) Versus Standard CPR Plus an ITD on Survival from Out-of-Hospital Cardiac Arrest

Further Study Details:

Primary Outcomes: Survival to hospital discharge with good neurologic recovery (Modified Rankin Score 3 or less)

Secondary Outcomes: Rate of adverse events; Return of spontaneous circulation (ROSC); Survival to 1 hour; Survival to hospital (e.g. intensive care unit) admission; Survival to 24 hours; Survival to 30 days; Survival to 90 days; Survival to 365 days; Neurological recovery at hospital discharge, 30 days, 90 days and one year; as measured by: Cerebral Performance Category (CPC), Overall Performance Category (OPC) and Health Utilities Index Mark 3 (HUI3); Cognitive Abilities Screening Instrument (CASI),

Expected Total Enrollment: 2450

Study Start: 2005-10

Despite receiving conventional, standard cardiopulmonary resuscitation (S-CPR), most patients who experience out-of-hospital cardiac arrest die prior to arriving at a hospital. At the present time, the hospital discharge rate following out-of-hospital, non-traumatic cardiac arrest in adults in the United States is estimated to be <5%. Many factors contribute to the currently poor survival statistics, including the inefficiency of the technique itself. CPR provides only 10% to 20% of normal myocardial perfusion, and only 20% to 30% of physiologically normal cerebral perfusion.

A new method of CPR that combines active compression decompression (ACD-CPR) and an impedance threshold device (ITD) (ACD-CPR+ITD), has been shown in animal models and in clinical trials conducted in Europe to provide significantly more blood flow to the vital organs and to improve survival rates when compared to S-CPR or ACD-CPR alone.

ACD-CPR+ITD works by decreasing intrathoracic pressure during the chest wall recoil (or decompression) phase of CPR, creating a vacuum within the thorax relative to the rest of the body. When compared with controls, use of ACD-CPR+ITD: a) enhances blood return to the thorax during the chest wall recoil phase, b) enhances blood flow to the heart and brain, c) provides real-time feedback to rescuers to maintain high quality CPR, d) improves overall CPR efficiency and, as a result of the foregoing, e) improves short-term survival rates.

The sponsor and others recently evaluated the effectiveness of the combination of conventional, manual standard CPR±ITD in animals and humans. The ITD increased short-term survival rates in these studies as well. Two clinical trials were performed in Milwaukee, Wisconsin under IDE (#G980125). Both compared S-CPR with either a sham (non-functional or placebo) or active (functional) ITD. The results from the hemodynamic study demonstrated that systolic blood pressure, the primary endpoint, increased from approximately 45 mmHg with the sham ITD to approximately 85 mmHg with the active ITD (P<0.05). Intensive care unit admission rate was the primary endpoint of the clinical outcome study.

Comparisons: The objective of this 3-arm, multi-site, randomized, pivotal IDE clinical trial is to compare survival to hospital discharge with neurologic recovery rates in subjects receiving S-CPR, ACD-CPR+ITD, and S-CPR+ITD following out-of-hospital cardiac arrest in well-established American emergency medical services systems.

## Eligibility

Ages Eligible for Study: 18 Years - N/A, Genders Eligible for Study: Both

### Criteria

Inclusion Criteria:

1. Adult subjects initially presumed or known to be 18 years of age or older
2. Subjects who present with out-of-hospital cardiac arrest from presumed cardiac etiology and who receive CPR by EMS personnel for at least one minute
3. Subjects whose airways are managed with a cuffed ET tube, Combitube or laryngeal mask airway or facemask.

#### Exclusion Criteria

1. Adult subjects presumed or known to be < 18 years of age
2. Subjects with known or likely traumatic injuries causing cardiac arrest or cardiac arrest of presumed non-cardiac origin
3. Subjects with pre-existing DNR orders
4. Subjects with signs of obvious clinical death or conditions that preclude the use of CPR
5. Family or legal representative request that the subject not be entered into the study
6. Subjects experiencing in-hospital cardiac arrest
7. Subjects with a recent sternotomy with wound not appearing completely healed (if unknown) or less than six months (if known)
8. Subjects who received less than one minute of CPR by EMS personnel
9. Subjects with a complete airway obstruction that cannot be cleared or in whom attempts at advanced airway management are unsuccessful
10. Subjects intubated with a leaky or uncuffed advanced airway device or presence of stomas, tracheotomies or tracheostomies
11. Subjects who re-arrest and are encountered by EMS within 365 days of the index cardiac arrest

## ► Location and Contact Information

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## ► More Information

Advanced Circulatory Systems, Inc. home page  
<http://www.advancedcirculatory.com>

Medical College of Wisconsin - ResQ Trial home page  
<http://www.mcw.edu/resqtrial>

## Publications

Wolcke BB, Mauer DK, Schoefmann MF, Teichmann H, Provo TA, Lindner KH, Dick WF, Aeppli D, Lurie KG. Comparison of standard cardiopulmonary resuscitation versus the combination of active compression-decompression cardiopulmonary resuscitation and an inspiratory impedance threshold device for out-of-hospital cardiac arrest. *Circulation*. 2003 Nov 4;108(18):2201-5. Epub 2003 Oct 20. : 14568898

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Lurie K, Voelckel W, Plaisance P, Zielinski T, McKnite S, Kor D, Sugiyama A, Sukhum P. Use of an inspiratory impedance threshold valve during cardiopulmonary resuscitation: a progress report. *Resuscitation*. 2000 May;44(3):219-30. Review. : 10825624

Plaisance P, Lurie KG, Payen D. Inspiratory impedance during active compression-decompression cardiopulmonary resuscitation: a randomized evaluation in patients in cardiac arrest. *Circulation*. 2000 Mar 7;101(9):989-94. : 10704165

Mauer DK, Nolan J, Plaisance P, Sitter H, Benoit H, Stiell IG, Sofianos E, Keiding N, Lurie KG. Effect of active compression-decompression resuscitation (ACD-CPR) on survival: a combined analysis using individual patient data. *Resuscitation*. 1999 Aug;41(3):249-56. : 10507710

Pirralo RG, Aufderheide TP, Provo TA, Lurie KG. Effect of an inspiratory impedance threshold device on hemodynamics during conventional manual cardiopulmonary resuscitation. *Resuscitation*. 2005 Jul;66(1):13-20. : 15993724

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