



CONVERT SCA Trial & The Houston Fire Department

CONVERT Study Sponsor

ZOLL Medical Corporation

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Trial Location

- **Houston Fire Department**
- **Houston, TX, USA**
 - **Urban, Suburban and Rural.**

Background

- Every year, 325,000 Americans die because of Sudden Cardiac Arrest (SCA)— their hearts suddenly stop beating normally and they are not able to be revived. Currently, only about 5 percent of victims survive; 95 percent will die from SCA. This study will hopefully shed new light on the best way to improve survival rates.

Trial Design

This research study will compare two methods of delivering defibrillations.

- Defibrillation means that an electrical current is passed through a patient's heart when it has stopped beating due to cardiac arrest.
 - 1) Normally chest compressions have to stop for the defibrillation so that rescuers are not accidentally shocked.
 - 2) However, when a machine is providing the compressions there is no need to stop the compressions to give the shock. At this time it is unknown if shock during compressions will improve survival or not.

Trial Stages

- Run-in stage: (approximately 2 months duration).
 - start randomization & treatment protocol, begin patient enrollment.
 - test trial logistics & gather patient data.
- Trial period: Patient randomization and gathering patient data or until statistical significance is shown (expected number of patients = 3000).
- End of Trial: 18-24 months after the run-in phase is completed.
- Data analysis will take place after the trial has been completed and soon thereafter the results will be published. This information will then be disclosed to the general public and the medical community.

CONVERT Trial Objective

The primary objective is to show mechanical CPR with defibrillation delivered during chest compressions is non-inferior to mechanical CPR with defibrillation delivered during the standard pause associated with an AED when the mechanical chest compression device is used as a adjunct therapy to manual CPR.

Trial Endpoints

- Primary- Shock success, defined as the termination of ventricular fibrillation or pulseless V-tach with a return of organized rhythm of 40 bpm or greater observed in the subsequent pause for rhythm analysis.
- Secondary- Return of spontaneous circulation(ROSC) at arrival to the Emergency department.

ZOLL AED Pro External Defibrillator

- The FDA cleared ZOLL AED Pro, intended for use by appropriately trained (such as ACLS or BLS certified) rescuer, is a portable, battery powered automated external defibrillator (AED) that uses voice prompts and visual messages to provide feedback to a user attempting a cardiac arrest rescue.



ZOLL AutoPulse Resuscitation System Model 100

- The AutoPulse Resuscitation System Model 100 will be used in this trial and is manufactured by ZOLL Medical Corporation. The AutoPulse Resuscitation System Model 100 is an automated, portable, battery powered device that compresses the chest of an adult human as an adjunct to manual CPR.



Risks

- There is the risk of a subject's privacy and medical condition being exposed

Benefits

Benefits Associated with Chest Compressions

- Increased coronary perfusion pressure and blood flow
- Increased cerebral perfusion and blood flow
- Increased likelihood of successful defibrillation
- Increased likelihood of return of spontaneous circulation
- Increased likelihood of survival from cardiac arrest

Benefits Associated with Electrical Defibrillation

- Increased likelihood of return of spontaneous circulation
- Increased likelihood of survival from cardiac arrest

Benefits Associated with Simultaneous Chest Compressions and Electrical Defibrillation

- Decreased or minimized pre- and post-shock pauses
- Reduction of defibrillation threshold
- Increased coronary perfusion pressure
- Increased myocardial oxygenation prior to defibrillation

Benefits

There is no financial impact to the city or subject regarding the participation in this trial

Subjects Included in The Trial

Candidates for this trial must meet **all** of the following Inclusion criteria:

- Subject is ≥ 18 years old;
- Out of Hospital setting Cardiac Arrest(OOHCA);
- Non-traumatic arrest of presumed cardiac etiology (PCE)

Subjects to be Excluded in the Trial

Candidates will be excluded from the trial if **any** of the following conditions are present:

- Subject that do not meet the patient parameters of the AutoPulse device.
- Subject is a ward of the state;
- Subject is a prisoner;
- Subject presents with a traumatic arrest (i.e., blunt or penetrating trauma)*;
- Arrest due to exsanguination, strangulation, smoke inhalation, drug overdose, electrocution, hanging, drowning;
- Known or clinically apparent pregnancy; or
- Do Not Attempt to Resuscitate (DNAR) order

Food and Drug Administration (FDA)

- This study will be performed under the Code of Federal Regulations 50.24, Exception from Informed Consent Requirements for Emergency Research
- This states that human subjects are in a life-threatening situation and will be unable to give their informed consent as a result of their medical condition

Oversight

- Sponsors of clinical investigations involving human drugs, biological products, medical devices, and combinations thereof are required to provide oversight to ensure adequate protection of the rights, welfare, and safety of human subjects and the quality of the clinical trial data submitted to FDA.

Institutional Review Board (IRB)

- An Institutional Review Board (IRB) is a committee established to review and approve research involving human subjects. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines.
- The IRB that will be used for the CONVERT SCA Trial is Baylor College of Medicine.
- The CONVERT SCA Trial is currently submitted and under review by the BCM IRB.
- Any pertinent safety data will continually be reported to the IRB for review.
- A thorough report will be submitted to the IRB annually for them to analyze and give their approval for continuation of the study.

Data Safety Monitoring Board (DSMB)

- The DSMB is independent from the Sponsor, the Investigators, or anyone involved in the clinical care of the trial subjects. Members will not have scientific, financial, or other conflict of interest related to the Sponsor or the Investigators. DSMB members must sign a non-conflict of interest statement in this regard.
- The DSMB will review all safety data from the CONVERT SCA trial and make recommendations based upon the safety analyses. It will be responsible for developing a charter. The frequency of the DSMB meetings will be determined prior to trial commencement; however, the DSMB may call a meeting at any time if there is a reason to suspect safety is an issue.

FDA

- The FDA will be the third agency with oversight on this study.
- They will continuously monitor the study for protocol compliance and safety of the subjects.

CONVERT TRIAL OPT-OUT

- Upon public notification of the trial any member of our community who does not wish to be enrolled may request an opt-out bracelet free of charge
- Individuals will be given a number to call and the bracelet will be immediately shipped to the specified address
- Care providers are trained to NOT enroll citizens wearing the bracelet

Questions?