

ALPS Risk/Benefit Public Announcement

Researchers at the Medical College of Wisconsin are studying the best way to treat adults in cardiac arrest.

This notice is to inform you of a research study looking at adult patients with cardiac arrest. The study will compare heart rhythm medicines that can be used during cardiopulmonary resuscitation (CPR) for cardiac arrest. The goal of this research is to help more people live after cardiac arrest. This study will affect people helped by the Milwaukee County Emergency Medical Services (EMS) System. This study began in March 2012 in Milwaukee County and will likely stop in December 2015.

What happens during cardiac arrest?

Cardiac arrest means that a person's heart stops beating. When this happens, blood does not reach important organs like the brain, lungs, or kidneys. This can injure these organs. When the heart stops beating, CPR should be started to help get blood to the body. CPR is usually done until the heart is working normally again. During regular CPR, defibrillation (electricity shocking the heart back into the right rhythm) can be used if the heart is not beating in a way that pumps blood to the body. Medicines can be used to help defibrillation get the heart to beat in a way that pumps blood, but researchers do not know if medicines used are better than giving no medicines at all.

Why do we need to do this research?

Right now, researchers do not know whether using heart rhythm medicines are better than giving no heart rhythm medicines if shocking does not work in CPR. This research study is comparing two medicines currently used during CPR as well as looking to see if not giving medicines at all is better. People in this study will be randomly chosen to be in one of the three groups. All patients will receive all other standard treatments for cardiac arrest. The researchers will find out if people will be more likely to live if they receive one of the medicines or no medication.

Are there risks to this research?

All research contains risks. Anyone who has CPR has a risk of damage to the brain, whether or not they are in this study. It is possible that survivors in one group may have more damage to the brain. Researchers will watch for this and stop the study if this happens. Possible reactions to the study drugs can be seizures, a severe drug allergy, or a slow heartbeat that may require a pacemaker (a small device placed under the skin to speed up the heart beat). Other potential risks for any patient that has any method of CPR include fluid build-up in the lungs, low blood pressure following revival, airway bleeding, pneumonia, bacteria in the blood stream, bleeding in the brain, stroke, seizures, bleeding requiring blood transfusions, surgery, repeat cardiac arrest, rib fractures, sternal fractures, or internal organ injuries. These potential risks are not expected to be different with either type of chest compressions. However, researchers will watch for this and stop the study if this occurs. Every precaution will be taken to assure safety.

What is the benefit of this research?

This study may help others in the future. One type of heart rhythm medicine used in CPR could have better results than the other. There is potential that a person in this study could have an increased chance of survival with one of the medicines, but that benefit is not guaranteed. People will not receive money for being in this research study and it will not cost a person anything. All information obtained from this study will remain private and confidential. The findings from this study will be presented at meetings and published in scientific journals, but information that could identify a person will not be used.

If you are an adult in Milwaukee County and have cardiac arrest, you may be in this study.

Cardiac arrest is an emergency and the paramedics have to act quickly to treat a person. This means that there is no time to get permission. People with cardiac arrest are unconscious and cannot agree to join. In studies like this, a person's consent is not possible. This is called an exception from informed consent for emergency circumstances. That means, if you do not want to be in this study, you must request that you not be included. You will be given a bracelet to wear that tells emergency services that you are not part of the study. You will still get regular CPR if needed. The U.S. Food and Drug Administration requires that researchers notify communities in cases when consent is not possible due to an emergency (FDA Code of Federal Regulations, Title 21, Section 50.24).

If you do not want to be in this study, you can let the researchers know.

If you have questions or concerns about this study or you do not want to participate, please contact Dr. Tom P. Aufderheide, either by phone (414-805-6493), mail (Department of Emergency Medicine, 9200 W. Wisconsin Ave., Froedtert Hospital East, PV1, Milwaukee, Wisconsin 53226 or email (RRC@mcw.edu), or visit the web site at (www.mcw.edu/ROCALPS). Feedback from the community may be used to change the study.