CCC 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. This study will compare regular cardiopulmonary resuscitation (CPR), which is when compressions (pushing on the chest to move blood) are stopped to give breaths, versus CPR using chest compressions that are not stopped while breaths are given. The goal of this research is to help more people live and reduce brain damage after cardiac arrest. This study will affect people served 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.

Why do we need to do this research?

Right now, researchers do not know the best way to perform CPR. This research study is comparing two ways to perform CPR to find out which is best. The current way to perform CPR is to stop chest compressions to give breaths. Some people in the study will receive the current CPR, which is when chest compressions are stopped to give breaths. Other people in the study will have CPR where the chest compressions are not stopped while breaths are given. Certain EMS areas are performing one type of CPR and other EMS areas, the other type. This is switched periodically throughout the study. The researchers will find out if people will be more likely to live or have fewer problems from cardiac arrest if they receive one type of compressions or the other.

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. 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. There is potential that a person in this study could have better CPR and increased chance of survival with one of the types of

compressions, 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/ROCCCC). Feedback from the community may be used to change the study.