REMOTE ISCHEMIC CONDITIONING TO ENHANCE RESUSCITATION (RICE) TRIAL

STUDY LOCATION

Physicians and other providers at Harborview Medical Center are planning to perform the Remote Ischemic Conditioning to Enhance Resuscitation (RICE) Trial. This research study will be conducted in the emergency department at Harborview.

STANDARD CARE

If you have out-of-hospital cardiac arrest in Seattle, paramedics may resuscitate you and take you to Harborview. If they do, you may be eligible for enrollment in the study. Out-of-hospital cardiac arrest is a loss of mechanical activity of the heart in the field. Quick restoration of blood flow (sometimes called reperfusion) is essential to reduce the chance of death after cardiac arrest. After resuscitation from cardiac arrest and transportation to hospital, standard care includes cooling of the body to reduce heart and brain injury, use of a machine to support breathing, and drugs to rest the brain. It may also include coronary angiography, which consists of placing a small catheter into an artery, check whether blood flow to the heart is reduced, and reopening the blockage if one is identified. With all of these standard treatments, about half of patients taken to hospital after cardiac arrest survive to discharge.

EXPERIMENTAL INTERVENTION

This experimental procedure is called remote ischemic conditioning (or RIC). This consists of applying brief episodes of ischemia then reperfusion to an organ or limb distal to the heart by inflating a blood pressure (BP) cuff around a limb to try to reduce heart injury after restoration of blood flow. Studies in animal with cardiac arrest as well as in humans with acute myocardial infarction suggest that RIC before or after restoration of blood flow may reduce injury to the heart and improves outcomes.

STUDY METHODS

Eligible subjects will be randomly allocated (like a coin toss) to standard care or standard care and the experimental procedure.

Potential study subjects will be identified when they arrive at the Harborview Emergency Department. We expect that we will enroll 30 subjects over a one-year period. The study intervention lasts for 30 minutes. After that, subject's participation is limited to careful and confidential review of their medical record by research staff until the subject is discharged from hospital.

All patients will receive standard care. Half will also receive active RIC; the other half will not. Which patient receives RIC, and which does not will be determined at random (like a coin toss). A standard blood pressure cuff and disposable plastic clamp will be used to apply RIC by three cycles of 5 mins. inflation to 200 mmHg followed by 5-mins. deflation of a blood pressure cuff on an upper arm. The cuff occludes the artery; the clamp maintains pressure in the air bladder of the cuff during the inflation periods.

RISKS

Application of a blood pressure cuff to the skin may be associated with adverse local effects such as pain or thrombophlebitis (i.e., inflammation of veins). RIC might modify the innate immune system, and so could contribute to infection or mask its diagnosis although no such signal has been detected in previous trials of RIC. More than 12,000 patients with other clinical conditions have completed trials of RIC with no reported serious adverse events.

If you are enrolled in this trial, all of your medical information will be kept strictly confidentially. You would not receive any personal benefit from this trial. You would be able to withdraw from the study at any time. Your withdrawal would not affect your care at Harborview.

HUMAN SUBJECTS ISSUES

Informed consent will not be obtained for most subjects. RIC must be started as soon as feasible (e.g., within 30 minutes of patient arrival) to try to reduce heart injury. When patients are resuscitated from cardiac arrest and transported to hospital, they are usually unconscious. Family members or legally authorized representatives are usually not present during the first half hour after patients are resuscitated and transported to hospital. If a family member is present within 30 minutes of arrival, we will obtain their consent prior to a subject's enrollment. If a family member is present and does not provide consent, we will not enroll the subject. If no family member is present during this time, we will enroll an eligible subject. After enrollment, we will contact all enrolled subjects and their family member to give them an opportunity to opt-out of ongoing participation.

Community input is important before we start enrolment in this study. Patients who are resuscitated from cardiac arrest are not able to make decisions for themselves when the first arrive at an emergency department. If you wish to opt out of enrollment at any time, you may contact Dr. Graham Nichol at 206 521 1728 or RICSTUDY@UW.EDU. You will be provided a bracelet that you can wear which states “NO RIC STUDY.”

SUPPORT
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