SODIUM NITRITE FOR OUT OF HOSPITAL CARDIAC ARREST

Researchers:
Francis Kim, MD
Michele Olsufka, RN
Deborah Sampson

Department/Division
Medicine/Cardiology
Medicine/Cardiology
Medicine/Cardiology

Phone
(206) 744-8712
(206) 744-5223
(206) 744-5224

24-hour emergency telephone number is (206) 744-3000.
This is the Harborview paging operator, ask them to page one of the investigators above.

Researchers' statement

Throughout this document we use the expression “your family member”. If you are the subject who was enrolled in this study, “your family member” refers to you.

Your family member recently experienced a cardiac arrest and was treated by the Seattle Fire Department or the King County Emergency Medical Services. During that time he/she was enrolled in the “Sodium Nitrite in Out of Hospital Cardiac Arrest” study. The purpose of this form is to give you information about the study. Federal regulations usually do not allow patients to be enrolled in a study without their informed consent or without the consent of their legally authorized representative. However, in certain limited situations, such as emergency medicine research, the U. S. Food and Drug Administration (FDA) does allow some studies to be conducted without prior consent. In these cases, a person treated in the study must be notified about it and permitted the opportunity to withdraw from continued participation. This is why this information is being given to you now.

PURPOSE OF THE STUDY

The purpose of the study is to determine whether giving the drug, sodium nitrite, to persons in cardiac arrest will result in better survival and improved brain function. Following cardiac arrest, the heart and brain are often injured due to a lack of blood and oxygen. Some patients will recover and wake up. However, a majority of patients will never recover. Based on studies on animals and on patients who are admitted to the hospital following cardiac arrest, the administration of sodium nitrite has been shown to improve oxygen delivery to the heart and brain and increase the chances of recovery after cardiac arrest. This medication is given into the veins through an I.V. (small needle in the vein). Giving sodium nitrite to cardiac arrest patients admitted to the hospital is safe. Also, animal studies have shown that the greatest benefits of sodium nitrite occur if it is given during cardiac arrest. The purpose of this study is to evaluate whether Seattle and King County paramedics can safely and effectively give sodium nitrite in patients during cardiac arrest. In addition, we want to see if there are indicators of clinical benefit (survival and brain function). In this study, a total of 1500 patients with out-of-hospital cardiac arrest in Seattle and King County will
be enrolled. Patients will receive either two different doses of IV sodium nitrite (45 mg or 60 mg) or placebo (a sterile salt water solution) during resuscitation by paramedics.

STUDY PROCEDURES

Your family member was enrolled in the study by the Seattle or King County paramedics following his/her cardiac arrest. Your family member was eligible for the study because the paramedics were providing treatment for cardiac arrest. As part of the standard treatment of cardiac arrest your family member had an I.V. placed in his/her vein. Your family member then received either 45 mg of sodium nitrite, 60 mg of sodium nitrite or a placebo. In Seattle the paramedics or medical personnel at the emergency department may have taken a small amount of blood (2-3 tablespoons) in order to measure the blood level of sodium nitrite. All other care during your family member’s resuscitation was according to Seattle and King County protocols.

All treatments and procedures related to this study were completed by the paramedics at the time that the cardiac arrest occurred. Nothing further is required on your family member’s part.

As part of your family member’s participation in this study, we now request permission to look at his/her medical records generated during the treatment of the cardiac arrest to determine the effect of the study treatment.

RISKS, STRESS, OR DISCOMFORT

Review of the medical record has risks related to your family member’s privacy and confidentiality. We have taken special measures to protect this privacy and confidentiality including our pledge to do so; keeping this information in a secure, locked password protected location; and destroying any connection between it and your family member’s identity after the study is completed.

ALTERNATIVES TO TAKING PART IN THIS STUDY

The best known treatments were provided to your family member during his/her cardiac arrest. Because of the emergency circumstance at the time of the cardiac arrest, being enrolled in this study was not optional. However, your family member’s ongoing participation, allowing review of medical records for the effect of the treatment received, is optional.

BENEFITS OF THE STUDY

Your family member received the best possible care by the Seattle Fire Department or King County Emergency Medical Services, during which time the best known treatments were given. There is no further direct benefit to your family member from being in this study. However, your family member’s participation is the study will benefit many other patients with cardiac arrest, by helping to find better treatments for this condition. Additional information about this study is contained in the following web address: http://www.uwmedicine.org/patient-resources/nitrite-study-information

SOURCE OF FUNDING

This study and members of the study team is receiving funding from the National Institutes of Health (NIH).

CONFIDENTIALITY OF RESEARCH INFORMATION

Your family member’s name and other identifying information will be assigned a unique identification code (ID). This study ID will not include any information that can identify your family
member. All of the information we collect from your family member’s medical record will be coded with the study ID. The master list that links your family member’s identify information to the study will be kept in a separate locked files and/or a password protected computer database.

Government or university staff sometimes reviews studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your family member’s records may be examined. The reviewers will protect your family member’s privacy. The study records will not be used to put your family member at legal risk of harm. The U.S. Food and Drug Administration (FDA) reserves the right to review study data that may contain identifying information.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

OTHER INFORMATION

You may choose not to allow your family member to be in this study, and you may withdraw them from the study at any time without penalty or loss of benefits to which they are entitled. Your family member will not be paid for taking part in this study. Your family member or his/her insurer will not be charged for any procedure related to the study. It is your family member’s responsibility to pay for costs related to the treatment for the cardiac arrest and for standard clinical care.

If you choose to withdraw your family member from this study at any time please contact the researchers by calling (206) 744-5223. Withdrawal from this study means that no further information will be collected from your family member’s medical record from the date of withdrawal.

If you have any questions about this study please contact the research staff listed at the top of this sheet. If you have question about your family member’s rights as a research participant, please contact the University of Washington Human Subjects Division at (206) 543-0098.

RESEARCH-RELATED INJURY

If you think your family member has an illness or injury related to this study it is important that you promptly notify one of the researchers. You can call him/her at the number(s) listed at the top of this form. This number is monitored 24 hours a day.

The costs of the treatment may be billed to your family member or your family member’s health insurance just like other medical costs or it may be covered by the UW’s discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form. We will bill your family member’s health insurance for treating problems that result from his/her cardiac arrest or from standard clinical care. If your family member has no health insurance or your family member’s insurance refuses to pay, we will bill your family member.
**Legal Next of Kin’s Statement**

For patients who are unable to sign due to the nature of their illness, I as the Legally Authorized Representative (LAR) wish to voluntarily enroll him/her in this study. I have had the opportunity to ask questions. I give my permission for the investigators to review his/her medical records as described above. If I have questions about the research I may contact one of the Investigators listed on the first page. If I have any questions about the subject’s rights as a research subject, I can call the Human Subjects Division at the University of Washington at (206) 543-0098. I will receive a copy of this consent form.

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Researcher  
Subject  
Subject’s Medical Record (if applicable)