

What is this research study?

Several Emergency Medical Service Systems (EMS) and the hospitals that they serve have been selected to participate in a nationwide study sponsored by the National Institute of Health (NIH) National Heart, Lung and Blood Institute (NHLBI), called the IMMEDIATE Trial. This Trial will test whether the administration of an IV solution of Glucose, Insulin and Potassium, referred to as “GIK” is helpful to patients at the first signs of a heart attack.

Who will be enrolled in the study?

If you call 9-1-1 with symptoms of a heart attack and meet the study criteria, you may be enrolled in the IMMEDIATE Trial. Paramedics are trained to identify patients by following very strict inclusion criteria. If you are having heart attack symptoms, such as chest pain or shortness of breath, are at least 30 years old and have positive findings for a heart attack on your electrocardiogram (ECG or EKG), the paramedics caring for you may decide that you are eligible for the study. However, if you show signs of heart or kidney failure, you will not be considered for the study. If the paramedic believes that you meet all the study criteria, he/she will read an information card to you about the study and then give you the option to decline participation before starting the study drug.

Do I have to participate in the study?

You do not have to participate. If you do not want to participate tell the paramedic caring for you. Full informed consent will not occur prior to receiving the study drug. However, you or a family member will be provided with more detailed information about the study once you are medically stable at the emergency department at which time you can decide whether or not to continue with the study drug (Full informed consent process).

If I participate, what is involved in the study?

As part of the usual treatment, an intravenous (IV) is placed with a standard solution. If you participate, you will be randomly assigned an additional IV solution of either the study drug (GIK) or placebo. Half of the patients will get GIK and the other half will get placebo. A placebo is an inactive substance that looks exactly like the experimental drug, but is not expected to have any treatment effects. This means that you may or may not receive the GIK being tested. Which study drug solution you get is determined by chance; neither you nor the treating medical staff will know which you are getting unless it becomes medically necessary to know. You will receive the solution for 12 hours unless you are discharged, change your mind, or the treating physician feels that there is a clinical reason to stop the study solution.

If I participate, are there any other tests involved?

All usual treatments and care will continue while in the study and thereafter. Blood tests to look for enzymes that indicate a heart attack is occurring will be drawn as part of your routine care. Other blood tests to measure potassium and glucose levels will be drawn as a part of the study.

If I participate, is there any kind of follow-up?

You will be contacted three times during the following year to learn if any other medical problems have occurred since your initial hospital visit.

Are there any benefits to my participating?

The administration of GIK in the ambulance, given as early as possible after the onset of heart attack symptoms, may have protect the heart muscle from damage until further therapies are available at the hospital. There is no guarantee of benefit.

Are there any risks to my participating?

The study drug is easily administered and associated with few side-effects. Possible but infrequent side effects, associated with GIK are redness or inflammation at the IV site, change in blood sugar levels that may cause a feeling of weakness, dizziness, or thirstiness; elevated or lowered potassium levels that may result in a change of heartbeat or dizziness. The IV solution may also cause extra fluid in the body. You will be monitored for these problems and you will receive treatment if necessary.

What happens if I find out that I am not having a heart attack and the study solution was already started?

The study solution will be stopped. The research team will then contact you in approximately 24 hours to follow-up on the status of your health.

What if I change my mind about participating?

You are not required to participate. If you are enrolled in the study and you decide that you do not want to participate, you only need to tell the treating paramedic or physician that you do not want to be in the study.

Where can I get more information about the study?

Call the IMMEDIATE Trial Coordinating Center at 617-636-8787 or visit the web at www.IMMEDIATETrial.com for more information to see if your community is participating in this study.



Sponsored by the National Institute's of Health, National Heart, Lung and Blood Institute

