

Brockton
Information
Sessions

Information Sessions

1. Cape Verdean Festival

An IMMEDIATE Trial information table was set up at the Cape Verdean Festival on July 30, 2006. This annual event is sponsored by the Cape Verdean Association of Brockton, and attracts many of the city's Cape Verdean residents. Approximately 40 people visited the table, were given an overview of the study, and printed materials. Printed materials included the IMMEDIATE Trial Information Sheets (English and Portuguese), the IMMEDIATE Trial Brochure (English), as well as heart attack education materials.

2. Country Fair

An IMMEDIATE Trial table was set up at the annual Brockton Country Fair on September 9, 2006. An IMMEDIATE Trial Project Manager and Research Coordinator represented the Trial at the fair. Approximately 100 people attending the health fair visited the IMMEDIATE Trial table. A brief overview of the study was provided to adults who came to the table, and IMMEDIATE Trial Information Sheets were given out.

3. Senior Supper

Caritas Good Samaritan Medical Center hosts a monthly dinner and presentation for senior citizens. On October 17, 2006 Dr. Assaad Sayah, the Regional Principal Investigator, and Dr. Richard Herman the Caritas Good Samaritan Medical Center Investigator attended the Senior Supper and presented a Power Point presentation (copies of the slides follow) on the IMMEDIATE Trial. The 100 attendees had an opportunity to ask questions after the presentation.

4. Community Consultation / Informational Meetings

A number of community consultation meetings took place throughout the city of Brockton in order allow potential participants (residents) to express their opinions regarding the IMMEDIATE Trial. At each meeting the regional Investigator presented a Power Point presentation (see tab 4, video media) that was followed by a question and answer session. IMMEDIATE Trial Brochures were available and attendees were encouraged to share them with family and friends.

The following is a list of the Community Consultation / Information Meetings that were held:

- Temple Beth Emunah, Wednesday evening Bingo
- Brockton Housing Authority, Tenant Presidents Meeting
- Brockton Council on Aging Meeting
- Brockton Public Housing, Belair Towers



DATE: October 17, 2006

LOCATION: Good Samaritan Hospital
Senior Supper

PRESENTOR: Dr. Assaad Sayah,
Medical Director of Brockton
Emergency Medical Response

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What is the IMMEDIATE Trial?

A nationwide study that is testing whether giving an intravenous solution of Glucose, Insulin, and Potassium, (GIK) is helpful to patients at the first signs of a heart attack.

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Research Team and Sponsors

Research team:

- Brockton Emergency Medical Service (EMS)
Operated by American Medical Response (AMR)
- Brockton Hospital
- Caritas Good Samaritan Hospital
- Center for Cardiovascular Health Services
Research at Tufts-New England Medical Center

Sponsored by:

- National Institutes of Health
 - National Heart Lung and Blood Institute

EMSP 1/05

Why are we here?

- ✓ Enrollment in the Trial is being done during an emergency situation.
- ✓ Not feasible to obtain informed consent prior to starting the study drug.
- ✓ Patients may not be physically or emotionally able to understand the study and make an informed decision to participate.
- ✓ To test GIK at the earliest possible time, it must be initiated as soon as possible after the onset of symptoms.
- ✓ Provide the details of the study and hear your questions and comments

EMSP 1/05

Background

In the United States each year, there are...

- ❖ 1.2 million heart attacks
- ❖ 1.8 million unstable angina episodes
- ❖ 500,000 deaths: 300,000 out of hospital
200,000 in hospital

Early recognition and treatment of heart attack symptoms is very important

11/11/05

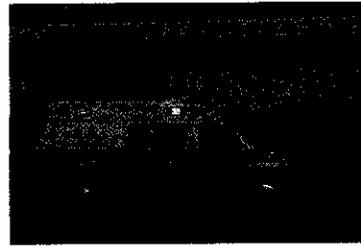
Heart Attack Warning Signs

- ❖ Chest Discomfort
(pressure, squeezing, fullness or pain)
- ❖ Discomfort in other areas of upper body
(both arms, back, neck, jaw, stomach)
- ❖ Shortness of Breath
(with or without chest pain)
- ❖ Other signs
(cold sweat, nausea, light-headedness)

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Why are we doing this study?

To test if GIK can prevent threatening heart attacks from occurring, and for heart attacks already underway, can decrease serious complications and death.



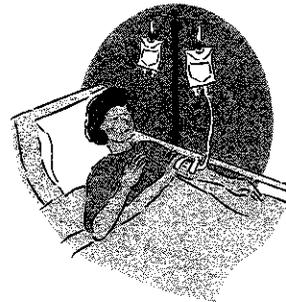
What is the study drug?

GIK

- Glucose: Sugar, provides fuel to the heart when there is a reduced blood supply.
- Insulin: Hormone, it moves the glucose into the cells.
- Potassium: Salt, found in many foods and stored in the blood.

Placebo

- Standard IV solution of sugar and water.



Randomization

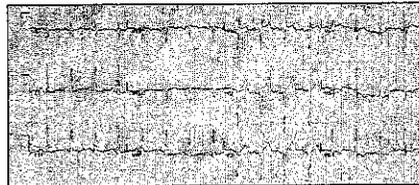
- ❖ 50% Placebo
- ❖ 50% GIK
- ❖ Double-blind



Who will be in the study?

Potential participants must meet all of the following conditions:

- ✓ 30 years of age or older
- ✓ Heart attack symptoms
- ✓ EKG that indicates a heart attack
- ✓ Paramedic believes the patient is very likely to be having a heart attack



Note: Patients with diabetes may be enrolled in the Trial. Patient's glucose levels will be monitored.

Who will not be in the study?

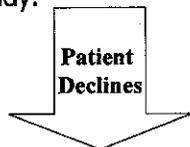
- ∅ Less than 30 years of age
- ∅ Unconscious or unable to communicate
- ∅ Unable or unwilling to comply with study
- ∅ Undergoing dialysis for kidney disease
- ∅ Lungs congested with fluid
- ∅ Unstable medical condition, such as low blood pressure
- ∅ A prisoner

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How will a patient be enrolled?

Ambulance

- ❖ Patient meets study inclusion criteria
- ❖ Patients will not be provided with full informed consent prior to receiving the study drug.
- ❖ Paramedics will read an information card to the patient about the study.
- ❖ Patient may tell the paramedic that he/she **does not want** to participate in the study.



Standard of care continues



GIK or Placebo is started
Standard of care continues

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If enrolled, what happens?

Hospital

- ❖ Emergency department (ED) doctors will confirm diagnosis.
- ❖ Full informed consent will be obtained.
- ❖ GIK or Placebo will continue for 12 hours
- ❖ All other healthcare care will remain the same.
- ❖ Research staff will contact patient up to 3 times over the next year (30 days, 6 months and 1 year after hospital discharge).

What are the potential benefits of GIK?

- ❖ Increase survival
- ❖ Decrease or slow the damage to the heart
- ❖ Allow other treatments a better chance of working
- ❖ Reduce the chance of congestive heart failure

What are the risks?

- ❖ Redness, soreness or inflammation at the IV site.
- ❖ Potassium level changes (high or low) causing irregular heartbeat or dizziness.
- ❖ Blood sugar level changes (high or low) causing weakness, dizziness or thirstiness.
- ❖ Increased fluid in lungs
- ❖ Unknown or unanticipated risks

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Where is the study being done?

Multi-center (nationwide)

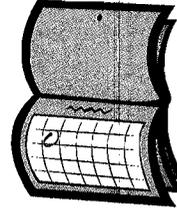
- ❖ Massachusetts Region (Concord and Brockton)
- ❖ Wisconsin (Milwaukee)
- ❖ Texas (Dallas)



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Study Duration and Timeline Plans for Enrollment

- ❖ Starts Fall 2006
- ❖ 2 year duration
- ❖ 24 hours a day / 7 days a week
- ❖ 15,450 patients to be enrolled nationwide



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Study Protocol

- ❖ Financial Benefits: None
- ❖ Costs: None
- ❖ Alternative Procedures: None
- ❖ Confidentiality
 - ❖ Information will remain confidential
 - ❖ Access to Medical Records
 - **Research Staff**
 - **Food and Drug Administration (FDA) and the National Institutes of Health (NIH)**
 - **Study Coordinating Center (Tufts-NEMC)**
 - **Hospital Institutional Review Board (IRB)**

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Summary

- ❖ You are having symptoms of a heart attack.
- ❖ You call 9-1-1 and Brockton EMS comes to care for you.
- ❖ Paramedic reads an information card about the study. You may decline participation.
- ❖ Study drug is started in the ambulance and continued for up to 12 hours.
- ❖ Paramedic notifies the emergency room doctor that you are enrolled in the study.
- ❖ You (or family member) receive a detailed description of the study (informed consent form) after arrival at the hospital and you are asked to decide if you would like to continue with the study.
- ❖ Standard of care continues.

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Questions or Comments?

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For more information please contact:

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Thank you!