Video Media

Littleton Cablevision videotaped the community consultation meeting that was conducted on September 20, 2006 at the Littleton Council on Aging to 19 senior citizens. Dr. Gert Walter, Investigator presented information on the IMMEDIATE Trial, utilizing the following Power Point presentation. The presentation aired seven times in the early evening between September 29, 2006 and October 8, 2006.

Immediate Myocardial Metabolic Enhancement
IMMEDIATE TRIAL
During Initial Assessment and Treatment in Emergency care

DATE: September 20, 2006

LOCATION: Littleton Council on Aging

PRESENTOR: Dr. Gert Walter
Medical Director of EMS
Emerson Hospital
Concord, MA

IMMEDIATE TRIAL

What is the IMMEDIATE Trial?

A nationwide study that is testing whether giving an intravenous (IV) 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
  - Emerson Hospital
  - Emerson Hospital Advance Life Support (ALS)
  - Center for Cardiovascular Health Services Research at Tufts-New England Medical Center
- Study Funding
  - National Institutes Health (NIH)
  - National Heart, Lung, and Blood Institute (NHLBI)

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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

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Background

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

- 1.2 million heart attacks
- 1.8 million unstable angina episodes
  (cardiac related chest pain events)
- 500,000 deaths: 300,000 out of hospital
  200,000 in hospital

Early recognition and treatment of heart attack symptoms is very important

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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.

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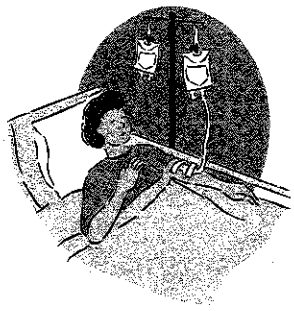
What is the study drug?

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.



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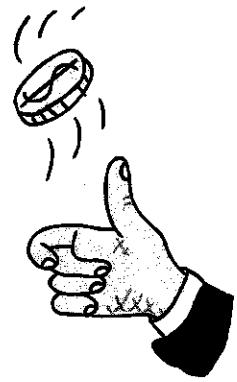
Randomization

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



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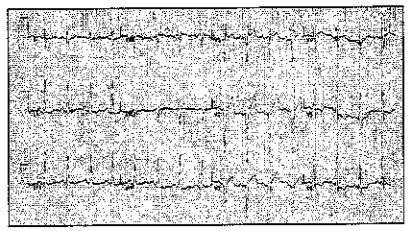
Who will be in the study?

Potential participants must meet all of the following conditions:



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

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Who will <u>not</u> 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?

<u>Ambulance</u>

- Patient meets study inclusion criteria
- Patients <u>will not</u> 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.
- If patient does not object, GIK or Placebo is started.

Patient Declines → Standard of care continues

Patient Does Not Decline → 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 follow up 3 times after hospital discharge (30 days, 6 months and 1 year after hospital discharge).

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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

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What are the risks?

- Unknown or unanticipated 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

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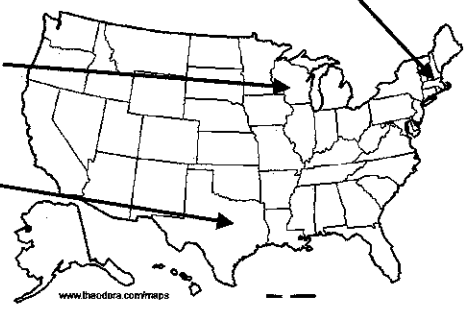
Where is the study being done?

Multi-center (nationwide)

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



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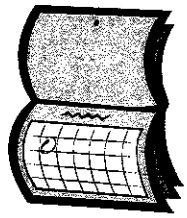
Study Duration and Timeline
Plans for Enrollment



- 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
    - Food and Drug Administration (FDA)
    - National Institutes of Health (NIH)
    - Study Coordinating Center (Tufts-NEMC)
    - Hospital Institutional Review Board (IRB)
    - Research Staff

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Summary

- You are having symptoms of a heart attack.
- You call 9-1-1 and Emerson Hospital EMS cares 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 drug.
- Standard of care continues.

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Community Consultation

- Feedback/Concerns
- Questions or Comments
- Discussion

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For more information please contact:

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Thank you!