

Stroke Study Meeting Set For Wednesday



Written by Carol Rock

Thursday, 17 July 2008

Ongoing study for experimental stroke treatment to be explained.

An information meeting to explain the risks and benefits of a stroke study being carried out by local paramedics and health care professionals is scheduled at noon Wednesday, July 23 at Henry Mayo Newhall Memorial Hospital. As part of the study, paramedics give stroke patients a dose of magnesium sulfate in the field, which may minimize brain damage.

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Jon Heller, an L.A. County paramedic/firefighter from Station 73 in Newhall, has been administering the treatment since its launch in 2003.

"Once the study is complete, they'll have data and evidence necessary to prove whether or not this drug should be part of the protocol," he said. "The most important part is that the patient gets enrolled, which we can do on site. They have to meet certain criteria, such as the onset of symptoms within the last two hours and we explain the criteria to the patient or the patient's family. They have to give permission for them to be part of the study.

Once they agree, we get them on a cell phone with a specific FAST-MAG doctor."



Once permission is obtained, paramedics administer the magnesium sulfate, which may be either the real thing or a placebo, for research purposes. The side effects are minimal; according to study doctors, the worst is a flushing of the patient's cheeks.

4-Regular community meetings are critical to the success of the study, which is sponsored by the National Institute of Health (NIH) National Institute of Neurologic Disorders and Stroke (NINDS), and is officially called the Field Administration of Stroke Therapy – Magnesium (FAST-MAG) Trial. This Trial is testing whether the administration of the natural chemical, magnesium sulfate, into a vein in the arm is helpful to patients at the first signs of a stroke.

Expanding the study to severe stroke patients requires performing the study using an "Exception from Informed Consent" under federal regulation 21 CFR 50.24. This regulation allows research to proceed without obtaining the consent of the research subject when patients are in a life-threatening situation requiring emergency medical intervention; the currently available treatments are unsatisfactory; participation in the study could provide a direct benefit to the patients enrolled the risks are reasonable, and the research could not be conducted without an exception from informed consent regulations. All of these apply to acute stroke, which is the third leading cause of death and leading cause of disability in the US.

Federal regulations only permit this type of research to be done when there has been consultation with community representatives to determine whether the research is consistent with ethical values and concerns of those who might become research patients.

The criteria for participating are simple: If you are having symptoms of a stroke, meet the study criteria, and 911 is called, you may be enrolled in the FAST-MAG Trial. The paramedics who respond to the 911 call are trained to identify potential study patients by following very strict criteria. If you are able to make decisions for yourself, you will be asked to read a study consent form, have any questions answered by a study doctor on cell phone, and decide whether or not you would like to enroll in the study.

You may be unable to make decision for yourself because the stroke has impaired your ability to use language or to think. If this happens and the study doctor finds that you meet all study criteria, you may still be enrolled in the study. You will only be enrolled in the study if family, friends, coworkers or other individuals who know you are with you at the time. The study doctor will explain the study to them and give family an opportunity to decline your participation. If you are alone and not able to make decisions, you will not be enrolled in the study.

Please attend the meeting to learn more about the study and to provide the investigators with your views of the study. For more information: Please visit www.fastmag.info or call the FAST-MAG Clinical Coordinating Center at (310) 794-6160.