

FAST-MAG Times

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FAST-MAG Makes History! First FAST-MAG Patients Are Enrolled

After months of preparation, including training and refreshing paramedics in 27 EMS provider agencies, the FAST-MAG study officially opened to patient enrollment on January 6, 2005. On January 27th, the long-awaited call arrived, and the first FAST-MAG patient was enrolled! As of press time on April 18, an additional six patients have been added to the enrollment list.

The first enrollment began at 1828 on January 27, 2005, when LA City Fire Department Rescue 59 was dispatched to an 80-year-old female complaining of left-sided facial droop and slurred speech. Paramedics George Mikami and Richard Aceves recognized potential stroke symptoms, and performed the mLAPSS, the FAST-MAG version of the Los Angeles Prehospital Stroke Screen, and determined it was positive. The study was offered to the patient who asked to know more. Mikami called the FAST-MAG enrolling physician, who successfully took the patient through the telephone consent process. When consent was obtained and the paramedics given the go-ahead to initiate the study drug, the 50-ml pre-hospital dose was started while in transit to UCLA Medical Center. The paramedics delivered the hospital dose of study drug to the UCLA ED nurse. The 24-hour maintenance infusion was begun immediately after completion of the prehospital dose. The time from symptom onset to study drug initiation in this patient was a

speedy 32 minutes, well within the 2-hour FAST-MAG time window!

Describing his first enrollment experience, paramedic Aceves relates, "Because it was our first enrollment, we had to think twice to make sure we had it right. It seemed to take a little extra time because of the newness of it, but we are

working the bugs out." Adds paramedic Mikami, "The FAST-MAG training was very adequate, and the quick guide reminder information (carried on the rescue) is definitely helpful." Mikami continues, "It will be interesting to see

how the study comes out. It's nice to be part of something that can help for stroke, to slow down or reverse the infarct. That's always exciting!"

The six enrollments that followed also proceeded smoothly. Many thanks to paramedics Terry Jack and Steve Stern (LA City Rescue 59), Becky Hegwer and Guadalupe Flores (LA City Rescue 19), Kyle Springer and Anthony Soffa (Burbank Fire Department Rescue 15), Bryan Howard and Rodger Polk (LA City Rescue 37), Frank Correa and William Brideau (LA City Rescue 74), and Brent Ruff and Michael Dula (LA City Rescue 77) for enrolling patients 2 through 7.

Dr. Sid Starkman, a FAST-MAG investigator at UCLA and one of the FAST-MAG enrolling physicians, took the first

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Paramedic George Mikami

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Fire Department Profiles

Burbank Fire Department

Founded in 1911, the Burbank Fire Department serves a population of 105,000, and averages about 9,000 calls annually, 85% of which are emergency medical service (EMS) calls. The paramedic program was added in 1975, and now has three full-time paramedic coordinators and 40 full-time paramedics who staff three rescue ambulances and one engine.

Burbank FD has the distinction of being, along with Long Beach Fire Department, the first group of paramedics in Los Angeles County to use Standing Field Treatment Protocols (SFTPs). According to Para-

medic Coordinator Captain Tom Lenahan, the department began with only three SFTPs. "We now have over 20," he says.

EMS calls are most frequently transported to Providence St. Joseph Medical Center, Glendale Adventist Medical Center, Glendale Memorial Hospital, with trauma transports to LAC-USC Medical Center, and Providence Holy Cross Medical Center.

Burbank FD paramedics are happy to be part of the FAST-MAG study, and recently completed their first, and FAST-MAG's fourth, enroll-

ment. "It's nice now that we've had one (enrollment), and that it went smoothly," says Lenahan. "If we can do something to help reverse some of the devastation of stroke, it's a very good thing."

The FAST-MAG Liaison to Burbank Fire Department is Randy Sanoff, RN.



Burbank FD Rescue 13

Meet Your Nurse Coordinator

Randy Sanoff, RN

Randy Sanoff, RN, Clinical Research Nurse with FAST-MAG, brings a wealth of experience to the team. A lifelong resident of the San Fernando Valley, Randy has found many professional challenges in Los Angeles, including emergency, flight, and critical care nursing, as well as a stint in "show biz" as an occupational health nurse for the movie studios. She is excited to be



a FAST-MAG team member, and feels that it is the ideal way to expand her career.

Randy is FAST-MAG liaison to Burbank Fire Department, Beverly Hills Fire Department, and Los Angeles City Fire Department Battalions 10 and 14. "My ED and MICN background make me particularly interested in the prehospital aspects of FAST-MAG, and I

feel fortunate to have the opportunity to work with the paramedics and other long-time friends from the prehospital system," she says.

Randy's site coordinator responsibilities include Providence St. Joseph Medical Center in Burbank, and Cedars-Sinai Medical Center. In addition, Randy serves as FAST-MAG liaison to the Los Angeles County Emergency Medical Services Agency.

First FAST-MAG Enrollments !

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enrollment call from the Rescue 59 paramedics. "The Los Angeles County FAST-MAG paramedics are truly pioneers in helping discover a therapy that could someday be a standard treatment for stroke," says Starkman. "They play a crucial role in this research and we

value their enthusiasm, skill and interest in making this a successful study."

FAST-MAG also thanks Nadia Yanni, RN, MICN, and Ala Wheelock, RN, of UCLA, for their participation in the first enrollment, as MICN and ED RN, respectively.

Thanks and congratulations to the growing countywide FAST-MAG team for helping to usher in a new era of stroke care in Los Angeles County!



FAST-MAG FEEDBACK!



Thanks again to all the paramedics who have enrolled

or attempted to enroll! Keep in mind that not every patient you call on will ultimately be enrolled. We are looking for a specific 1298 patients, not just any 1298 patients. Many patients may be mLAPSS positive but not eligible for FAST-MAG for a variety of reasons. Keep calling the enrollment lines for any potential FAST-MAG patient. The next enrollment could be yours!

We have enrolled 7 patients to date. All were properly enrolled and had study procedures performed correctly. Based on questions and comments from the paramedics who have screened patients for the study, some issues have come up which we feel deserve review to help all of us follow appropriate patient safety guidelines and enrollment procedures:

1. Patients **MUST BE** consented by the FAST-MAG enrolling physician. They cannot sign the consent form until they have completed the consent conversation with the enrolling physician and the physician has asked the paramedics to have the patient

sign the consent form. The study doctors alone are responsible for proper consent.

2. The FAST-MAG study kit, containing the field and hospital doses of the infusion, and the IV tubing, should be opened **ONLY AFTER** the enrolling physician confirms that the patient meets study eligibility, elicits consent, and instructs the paramedic to open the kit and administer the study drug.

3. The FAST-MAG study kit contains experimental study drug and must be handled within appropriate biomedical guidelines. Each paramedic rig has a specially numbered kit, which must be tracked. The kit must be used for a FAST-MAG patient or returned to the FAST-MAG nurse. It should not be released to any other person for any reason.

FAST-MAG is off to a great start, thanks to the concern, professionalism and efforts of the Los Angeles County paramedics. We are grateful for the enthusiastic calls we have received and the interest shown in this study, and very much appreciate your efforts on behalf of stroke patients in Los Angeles County.

THANK YOU!

To all ED/ICU/floor RNs & MDs at:

UCLA
Providence St. Joseph
LAC- Olive View

for successfully carrying out FAST-MAG hospital procedures for the first 7 enrolled patients!



The FAST-MAG study doctor is available 24 hours a day, 7 days a week, for enrollment or any study-related questions!

Please call the study doctor with any questions about the mLAPSS, consent process or any other FAST-MAG issue.



UPDATES

Enrollments:

7!

FAST-MAG patients enrolled as of April 18, 2005

FAST-MAG Hospitals

The following hospitals are now open for FAST-MAG enrollment:

Henry Mayo Newhall
LAC-Olive View
Northridge
Providence St. Joseph
Saint John's Health Center
San Dimas Community
Santa Monica-UCLA
UCLA
West Hills

Watch as the FAST-MAG "family" continues to grow!

Enrolling Paramedic Units

Thanks to the following LA County paramedic units for enrolling the first 7 FAST-MAG patients!

LA City Rescue 59 (2 enrollments)
LA City Rescue 19
Burbank Fire Rescue 15
LA City Rescue 37
LA City Rescue 74
LA City Rescue 77

Thanks for all your efforts!
FAST-MAG couldn't do it without you!

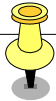
FAST-MAG CLINICAL TRIAL COORDINATING CENTER

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Visit FAST-MAG on the web!
www.fastmag.info

FAST-MAG

“Because Time is Brain”



FAST-MAG FAQ

Q. If the paramedic is unsure if the patient is competent or meets criteria, what should he/she do?

A. Whenever a patient meets study inclusion criteria (mLAPSS positive, patient age ≥ 40 and ≤ 95 , last known well time within 2 hours of potential treatment initiation, deficit present for > 15 minutes), the paramedic should seek patient/family permission to call the central enrolling physician. **If there are any questions concerning patient eligibility for enrollment or consent signing, the paramedic should call the FAST-MAG enrolling physician** who will review patient status and history to jointly make the decision with the paramedic.

What is FAST-MAG?

FAST-MAG (Field Administration of Stroke Therapy - Magnesium) is a clinical research study designed to test whether field administration of IV magnesium sulfate by paramedics improves the outcome of stroke patients when given within two hours of stroke symptom onset.

Patients who meet study criteria and in whom informed consent to participate is obtained will receive a bolus of FAST-MAG study drug (magnesium or placebo) in the field, followed by a 24-hour infusion of study drug in the hospital. Patients will be assessed by FAST-MAG key personnel at designated points over the three months following their stroke.

The study will enroll 1298 patients, involve up to 70 Los Angeles County hospitals, and more than 3,000 paramedics in 27 provider agencies. The study is funded by the National Institutes of Health, and approved by the California Statewide EMS Authority and the Los Angeles County EMS Agency.