

FAST-MAG Times

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FAST-MAG Clinical Coordinating Center Staff

Jeffrey Saver, MD
Principal Investigator

Sidney Starkman, MD
Co-Principal Investigator

Latisha Ali, MD
Investigator

David Liebeskind, MD
Investigator

Lucas Restrepo, MD
Investigator

Nurses Sanossian, MD
Investigator

Miguel Valdes-Sueiras, MD
Investigator

Fiona Chatfield, RN
Chief Nurse Coordinator

Sharon Craig, RN, BSN
Study Monitor

T. Keta Hodgson, RN
Gillian Devereux, RN
Molly Hoffman, RN
Annel Hernandez, RA
Editorial Staff

Back by popular demand. The best of FAST-MAG Times and FAST-MAG Update. All back issues are available at www.fastmag.info under “Newsletters.”

“But we had the perfect patient!”

In the FAST-MAG clinical trial, the enrolling MDs and paramedics work together as a team to ensure that all patients who are eligible for the study are enrolled. Paramedic screening for potential FAST-MAG study subjects is the first step in the enrollment process. Sometimes an mLAPSS-positive patient who meets *field* inclusion criteria cannot be enrolled in the study.

There are several reasons that a patient who initially seems to be an excellent study candidate may end up not enrolled in FAST-MAG. This is because study doctors have duties that they cannot delegate to others. First, they must determine if the patient can give informed consent. Does the patient understand what is being said; is the response appropriate? This can be a challenge if the person’s ability to speak has

been affected by the stroke. The enrolling MD must establish whether the problem is with slurred speech (dysarthria) or if there is a problem with understanding language (aphasia). The stroke experts who enroll patients in FAST-MAG are qualified by their training and experience to make this judgment.

By the rules governing research, if patients are competent (understand what is going on), they MUST provide consent for themselves. If a competent patient does not speak English or Spanish, a family member cannot give consent and the paramedic cannot “translate.” If the enrolling MD is unable to communicate with the patient on the phone and they are competent, they cannot be enrolled in the study.

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“We are very aware of the extra steps paramedics go through before they call the enrollment line and we share their disappointment whenever a call results in a non-enrollment.”

Assessing Facial Droop: Even the textbooks have it wrong!

Facial droop is probably one of the most misunderstood aspects of a stroke assessment – even for health care professionals. In the FAST-MAG trial, a patient meets criteria for screening by a physician, even if their only deficit is a facial droop.

Remember: If you find droop and it seems to be on the opposite side of the grip or arm includes a three-item motor exam: facial smile or grimace (droop), hand grip and arm strength. In order to qualify for FAST-

MAG, the patient must have a deficit in one of these three areas. Paramedics have demonstrated excellent ability to accurately assess grip and arm strength.

The most reliable approach to assess facial droop is during active smiling:

1. Ask the patient to smile or show their teeth
2. If the patient is unable to follow directions, mimic the action
3. The droop (or facial weakness/deficit) is on the **side that does not move or moves less** than the unaffected side

When we review run sheets for stroke patients NOT enrolled in the study, one

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... the perfect patient

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Patients who are not competent **MUST** have someone to provide consent for them. It is the enrolling MD's responsibility to determine competence.

The enrolling MD must determine if the patient fully meets study inclusion and exclusion criteria. Are there factors that might confuse our understanding of the effect of magnesium on functional outcome?

Do they have a condition that would make it unsafe to participate in the study? Paramedics already determine several key criteria, such as patient age and blood pressure; they only call the enrollment line for patients who pass the initial screen. However, there are additional factors involving medical judgments that only the enrolling MD can make. Researchers must comply with federal guidelines regarding the informed consent process and eligibility assessment. In the FAST-MAG clinical trial, the enrolling MDs are the individuals who have the final responsibility for making these determinations.

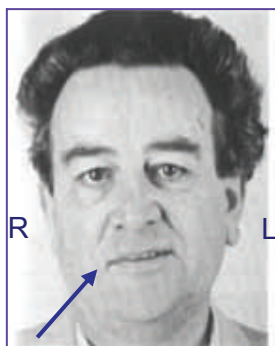
Data is collected on paramedic screened cases that will help researchers understand the general application of the study results. Thus even non-enrolled patients contribute to study results.

Speaking of non-enrollments, Dr. Jeffrey Saver, FAST-MAG principal investigator, says: "*We wish that every call to the enrollment line would result in an enrollment. We try to put every patient who meets trial criteria in the study. We are very aware of the extra steps paramedics go through before they call the enrollment line and we share their disappointment whenever a call results in a non-enrollment.*"

The enrolling MDs are extremely grateful to their partners in the field for identifying potential study patients. No matter the outcome of the call, **EVERY CALL COUNTS!**

Assessing Facial Droop

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of the most frequent findings is that the patient had only facial droop. Often-times these facial weakness/droop patients have slurred speech or aphasia caused by an acute stroke. Sometimes these findings are just described as altered but, when looked for, the facial asymmetry/droop is evident.

REMINDER: Patients need only one motor deficit for you to call the enrollment line.

UPDATES

Enrollments

1,169

(through December 31, 2010)

FAST-MAG Hospitals

The hospitals listed below are participating in FAST-MAG

Antelope Valley Hospital
 Beverly Hospital
 Brotman Medical Center
 California Hospital Medical Center
 Cedars-Sinai Medical Center*
 Citrus Valley – Intercommunity
 Citrus Valley – Queen of the Valley
 Encino Hospital Medical Center
 Garfield Medical Center
 Glendale Adventist Medical Center*
 Glendale Memorial Medical Center
 Good Samaritan Hospital
 Henry Mayo Newhall Memorial Hospital*
 Hollywood Presbyterian
 Huntington Memorial Hospital*
 Kaiser – Woodland Hills
 Kaiser – Sunset*
 Kaiser – West LA (Cadillac)
 Kaiser – South Bay (Harbor City)
 LAC – Harbor-UCLA Medical Center
 LAC – Olive View Medical Center
 LAC – USC Medical Center
 Lakewood Regional Medical Center
 Little Company of Mary – San Pedro*
 Little Company of Mary – Torrance*
 Long Beach Memorial Medical Center*
 Marina Del Rey Hospital
 Methodist Hospital of So. California*
 Mission Community Hospital
 Northridge Hospital Medical Center*
 Olympia Medical Center
 Palmdale Regional Medical Center
 Pomona Valley Hospital
 Presbyterian Intercommunity Hospital*
 Providence Holy Cross Medical Center*
 Providence Saint Joseph Medical Center*
 Providence Tarzana Hospital*
 San Dimas Community Hospital
 Santa Monica – UCLA Medical Center
 Sherman Oaks Hospital
 St. Francis Medical Center
 St. John's Health Center
 St. Mary Medical Center
 Torrance Memorial Medical Center*
 UCLA (Westwood) Medical Center*
 Valley Presbyterian
 Verdugo Hills Hospital
 West Hills Hospital & Medical Center
 White Memorial Medical Center*
 Whittier Hospital Medical Center – AHMC

*Approved Stroke Center

Paramedic Hall of Fame: July 22, 2010 through December 31, 2010

07/23/10	David Bernier Ryan Fogg Travis McAndrews	LA CO FD RS 116	08/21/10	Charles Brigance Tom Cavanaugh	LA CO FD RS 37
07/23/10	Jim Fernandez Dave Cavallero Eric Hammerstrom	LA CO FD RS 182	08/21/10	Jeff Johnson John Grapentin Travis Moore	La Verne FD RS 62
07/23/10	Brian Stephens Victor Duran	LA CO FD RS 29	08/22/10	Shannon Olson Matthew Verga	LA CO FD RS 106
07/23/10	Todd Caldwell Mike Noriega	LA CO FD RS 50	08/23/10	Bryce Lahiff Chris DuBois Scott Sherman	LA CO FD RS 11
07/24/10	Jeff Brinkman Jeremy Collings Eddie Martinez	LA CO FD RS 31	08/29/10	Christopher Sagara Sineoh Espaza	LAFD RA 41
07/29/10	Cliss Snyder Jorge Hoyos Robert Crew	S. Pasadena FD R 81	08/31/10	Richard Sutherland Nancy Stroud	LA CO FD RS 158
07/29/10	Tim Dougherty Doug Britton	LA CO FD RS 134	09/02/10	Justin Voyson Wes Blackwell	LAFD RA 209
07/31/10	Ed Villareal Mark Moyer	LAFD RA 47	09/05/10	Leo Dunn Joe Scamardo	LAFD RA 64
08/03/10	Anthony Hildebrand Steve Lund	Downey FD RS 642	09/05/10	Andrew Ronnow Michael Bennetts	LA CO FD RS 154
08/03/10	Reuben Estrada Tony Ferro	LAFD RA 84	09/06/10	Jeff Buterbaugh Josh Tibbett	LA CO FD RS 134
08/04/10	Rolf Ward Jeff Vargas	Long Beach FD RS 14	09/07/10	Josh Tibbett Kevin Poole	LA CO FD RS 134
08/05/10	Octavio Corona Taylor Byars Clarissa Leos	LA CO FD RS 19	09/09/10	Dominic Petta Nick Maza Russell Wilcox	San Marino FD RS 91
08/07/10	Stanley Miner Paul Mercado	LAFD RA 61	09/11/10	Chris Stradtner Paul Bellante	Santa Monica FD RS 5
08/08/10	Matt Recore Johnny Mancini	Santa Monica FD RS 3	09/15/10	Christian Gassler John Roberts Nicholas Gonzales Ron Cavataio	LAFD RA 7
08/08/10	Nektarios Markouizos Martin Magana Kory Knapp	Long Beach FD RS 13	09/15/10	Phil Dirkin Gary Wilks James McDonald	LA CO FD RS 39
08/10/10	Brian Cross Aaron Mungaray	LAFD RA 85	09/20/10	Mike Herdman Drew Pryor	Arcadia FD RS 106
08/10/10	Nick Marantz Manuel Gomez Lucio Andrade Steve Seaburn	Long Beach FD RS 10	09/26/10	Paul Rodriguez Steve Volz	Long Beach FD RS 9
08/11/10	Matt Verga Wade Elliott	LA CO FD RS 106	09/28/10	Alex Pacheco Tony Wu	LA CO FD RS 36
08/13/10	Ryan Schleiger Erick Ekstedt Josh Halbmaier James Hayes	Downey FD RS 642	09/28/10	Gregory Hoon Derek Heagy	LAFD RA 98
08/17/10	Ray Karsten Bruce Alpern Armando Ramirez	LA CO FD RS 111	09/29/10	Gary Wilks Philip Dirkin PT James McDonald	LA CO FD RS 39
08/17/10	Brenda Akins Sara Rathbun Calvin Wood	LA CO FD RS 173	09/30/10	John Orona Nick Ewing Christian Miller	Pasadena FD RS 34
08/20/10	Sam Chao Mike Brooks Ryan Resnick Rickey Cradle	Torrance FD RS 91	10/01/10	Rick Eagleston David Morales	LAFD RA 105
			10/02/10	Mike Harrison Danny Sanchez	Long Beach FD RS 9
			10/03/10	John Reyes Kelly Corcoran	LAFD RA 1
			10/04/10	Jeff Patterson Stan Bakey	Arcadia FD RS 105

Paramedic Hall of Fame: July 22, 2010 through December 31, 2010

10/04/10	Don Shaw Greg Whitmore	LAFD RA 63	11/10/10	Jeffrey Cordray Michael McDonough	LAFD RA 36
10/05/10	Mark Klein Mike Dmytrowicz	LA CO FD RS 158	11/10/10	Ken Myers Victor Khachatoorian	LAFD RA 55
10/05/10	Derek Moran Victor Oseguera	LAFD RA 46	11/12/10	Mike Buchs Jody Radtke	Torrance FD RS 96
10/08/10	Brian Smith William Prentice	LA CO FD RS 11	11/12/10	Ron Knopp William Aridzzone Brian Fisk	Long Beach RA 14
10/08/10	Mike Chapman Jon Ferguson	LA CO FD RS 182	11/14/10	Damon Grayson Zoltan Nagy	LAFD RA 25
10/08/10	Philip Olivas Chris Guerra Dan Dau	LA CO FD RS 40	11/16/10	Victor Khachatoorian Edward Hechanova	LAFD RA 55
10/09/10	Adam Hecht Travis Moore Kevin Greenway	LA Verne FD RS 62	11/16/10	Kristoph Wattson Chong Kim	Long Beach RA 17
10/10/10	Ryan Piper Jeff Winguard	LA CO FD RS 161	11/17/10	Michael McDonough Ricky Herrera	LAFD RA 36
10/18/10	Eric Gardner Nathan Wilmarth	LAFD RA 73	11/19/10	Stephen Zeimer Mr. Samudio	LAFD RA 29
10/18/10	Corey Schwartz Michael Greene	Compton FD RS 441	11/19/10	Jorge Guidos David Dantic Robert Ortiz	LA Co RS 32
10/19/10	Matt Rochman Scott Kwasigroch	LAFD RA 33	11/20/10	Daniel Stark Corey Taillon Man Sivaborvorn	LAFD RA 91
10/21/10	Dave Tannehill Mike White	San Marino FD RS 98	11/21/10	Andres Hidrogo Ryan Howes	LAFD RA 59
10/22/10	Sean Powers Eric French	LAFD RA 10	11/21/10	Aaron Mann Michael Contreras	LAFD RA 57
10/23/10	Jerome Woodcock Paul Medina	LAFD RA 38	11/22/10	Dreon Brown John Heller	LAFD RA 56
10/24/10	Curt Wasserman Chad Rolish	LAFD RA 94	11/22/10	David White James August	LA Co RS 36
10/28/10	Jerome Woodcock David Chavez	LAFD RA 38	11/26/10	Andres Hidrogo David Rodriguez John Shibuya	LAFD RA 59
10/28/10	Veronica Ponce Xavier Urquiza	LA Co RS 26	11/27/10	Jorge Guidos Jackson Reich Tim O'Donnell	LA Co RS 32
10/29/10	Shane Stocking Harvey Hewitt Andy McDaniel Scott Dewey	Monrovia RS 101	11/28/10	Tom Desmond Craig Youngdale Erick Strong Larry Randall	Manhattan Beach RA 21
10/31/10	Jason Keener David Lake	LAFD RA 87	11/29/10	Steve Maloof Andres Manzano	LA Co RS 40
11/01/10	Josh Hogan Dave Rosa Brian White	Long Beach RA 10	11/30/10	Ken Johnstone Keith Smith	LA Co RS 111
11/03/10	Chad Wells Geoff Dayne Michael Palacios	Santa Fe Springs RA 841	12/02/10	Mike Pelligrini Tim Anilian	LAFD RA 68
11/05/10	Sarah Stradtner Walter Patton Brendt Noon Milo Garcia	Santa Monica Eng 3	12/04/10	Lisa Tatham Tye Johnson Doug Carey	Long Beach RA 19
11/06/10	Brian Nielsen Greg Metz Ryan Fogg	LA Co RS 116	12/04/10	Peter Tagliere Edward Tumbleson Benjamin Guzman	LAFD RA 39
11/08/10	Daniel Ramirez Joshua Pickard Michael Campaña	LAFD RA 89	12/06/10	Anthony Ferro Doug DeYoung Tom Chamberlain	LAFD RA 84

Paramedic Hall of Fame: July 22, 2010 through December 31, 2010

12/08/10	Mike Contreras Paul Young	LAFD RA 66	12/18/10	James Woods Eric Biefeld George Navarro	LA Co RS 49
12/10/10	David Chavez Jerome Woodcock	LAFD RA 38	12/20/10	Carlos Garcia Steve Cox	Montebello Eng 55
12/13/10	Roger Peterson Eric Evans Octavio Corona	LA Co RS 19	12/21/10	Steve Wallace Greg Fierro	San Gabriel Fire RA 51
12/13/10	Shane Stocking Harvey Hewitt	Monrovia RS 101	12/23/10	Michael McGrady Bud Billips	LAFD RA 77
12/15/10	Sarah Stradtner Brendt Noon Milo Garcia Walter Patton	Santa Monica Eng 3	12/23/10	Landon Rupright Daniel Sandoval	LAFD RA 25
12/16/10	Chad Sourbeer Tim Scott Moses Vargas	LAFD RA 88	12/25/10	Leigh-Anne Orr Jon Burckle Sara Rathbun	LA Co RS 173
12/17/10	Shon Halborson Daniel Salazar Darnell Johnson	Compton Eng 41	12/31/10	William Aridzzzone Kristoph Wattson	Long Beach RA 19
Total 2010 Enrollments = 257					

Did you know?

FIELD EXCLUSION CRITERIA

If your patient's systolic blood pressure is greater than 220, they will not be enrolled in the FAST-MAG trial. In most cases, a blood pressure this high is because of a hemorrhagic stroke. While magnesium is safe for patients with bleeds, this protocol was designed primarily for ischemic strokes. You will find this criterion on the mLAPSS form with other field exclusion criteria (prisoner, homeless, on dialysis, nursing home resident). You do not need to call the FAST-MAG enrolling MD if the patient's systolic pressure is greater than 220.

FIELD DOSE

The "F" in FAST-MAG stands for FIELD (Field Administration Stroke Therapy – Magnesium). The study protocol requires that the field dose start before the gurney has crossed the threshold of the hospital. If it has not been started before then, the enrollment is canceled. Notify the enrolling MD that the study drug was not started. Do not reuse an opened kit (but do not discard it). Replacements for the kit and the consent form will be delivered within 24 hours.

Ten Quick Steps to a FAST-MAG Enrollment

1. Identify potential stroke patient and perform LAPSS
2. If LAPSS positive (all items are yes), determine destination
3. Find hospital specific consent
4. Introduce the study to the patient or representative
5. If patient interested, call the enrolling MD; keep family/friends close by
6. MD explains the study and obtains consent
7. When the MD says to do so, have the patient or representative sign and date the green pages
8. When the MD gives you the order, hang the **GREEN** field dose
*** Must begin field dose before crossing the ED threshold ***
9. Complete the transport
10. Give ED RN the informed consent, the **YELLOW** bag, the completed LAPSS (front and back) and a legible copy of the run sheet

FAST-MAG
Clinical Coordinating Center
1072 Gayley Avenue
Los Angeles, CA 90024

Visit FAST-MAG On The Web!
www.fastmag.info

FAST-MAG



Did you know?

Every patient eligible for FAST-MAG is eligible for all available treatments.

On-scene to door time

As first responders know, in stroke, “time is brain.” To minimize delay, FAST-MAG field activities were designed to take place in parallel with standard pre-hospital stroke care.

The FAST-MAG Paramedic Operations Committee ensures that study procedures are not causing substantial delays by monitoring on-scene to door times. For stroke, the national average for medic arrival on-scene to patient arrival at the ED is between 34 and 40 minutes. For the first 1,000 patients enrolled in FAST-MAG, the on-scene to door time is **35** minutes.

If the paramedic or the enrolling MD become concerned about delays in the process, or if the patient becomes unstable, either can abort the enrollment attempt.

RESEARCH 101: Informed Consent

Informed consent is a legal and ethical process to ensure that a potential study subject or a representative understands fully what it means to participate. It is the responsibility of the enrolling MD to provide complete information about the study and to ensure that the decision to participate is voluntary. No study procedures can be done until consent is obtained.

The consent process must be in the subject’s primary language. The consent form describes the study purpose, procedures and potential risks and benefits. It includes privacy protections and lists key contacts. Importantly, the consent form specifically states that the subject has the right to withdraw at any time. A key element of the process is that it cannot be coercive in any way.

It is the investigator’s responsibility to determine who provides consent. Patients do so if they are mentally competent to make decisions. If not, a legally authorized representative provides consent. The investigator ensures that the consent provider’s questions are answered.

“It is the responsibility of the enrolling MD to provide complete information about the study”

Consent for research differs from consent for emergency care. While emergency care can take place based on *implied* consent, research requires *explicit* consent. Each participating hospital has their own consent form, which includes authorization to release personal health information for research. For the FAST-MAG Clinical Trial, the study investigator is the enrolling MD. Pages requiring a signature are green and are tagged with stickers. The person who speaks with the study doctor signs and dates the green pages. The paramedic

does not sign the consent form.

The enrolling physician signs the consent by fax and copies are placed in the patient’s chart and given to the family. The original is filed with the patient’s study chart at the Coordinating Center.

The FAST-MAG consent process occurs in parallel with field activity. This process is crucial to ensure that FAST-MAG is conducted ethically and with the greatest respect for the dignity and autonomy of patients.

“The paramedic does not sign the consent form”