

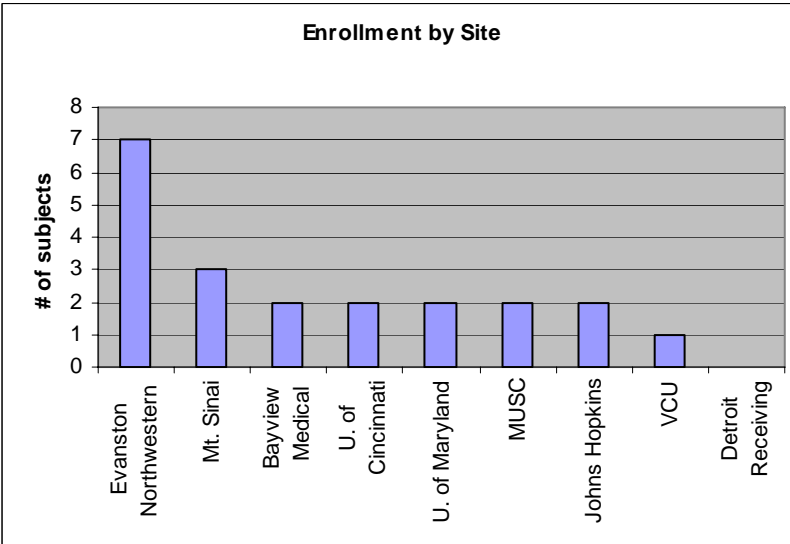
# MISTIE Study Monthly Newsletter



**MINIMALLY INVASIVE SURGERY PLUS TPA FOR INTRACEREBRAL HEMORRHAGE EVACUATION: MISTIE**

## Study Status, Site Participation

(last update: 9/28/2007)



## CT/ Radiology In-service

The coordinating center will soon be conducting in-services to equip coordinators and investigators with helpful information relating to the daily monitoring of patient status using CT. Featuring details about stability and volumetric measuring, the in-service will be a helpful tool in spreading best imaging practices among active sites in the trial.

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Site	Run-in	Randomized	Site	Run-in	Randomized
Evanston Northwestern	✓	6	Med. Univ. of S. Carolina	✓	1
Mt. Sinai Medical	✓	2	Johns Hopkins Univ.	✓	0
Bayview Medical	✓	1	Virginia Commonwealth	✓	0
University of Cincinnati	✓	2	Detroit Receiving Hospital		0
University of Maryland	✓	1			

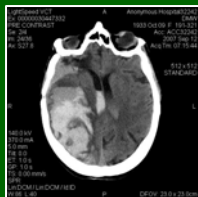
## Recent Enrollments

Congratulations once again go out to Dr. Issam Awad, his Research Coordinators (Judy O'Leary, RN, OCN, CCRP and Jenny Levin, MPH), and the rest of his MISTIE Study research team at Evanston Northwestern Healthcare in Evanston, Illinois for enrolling their SIXTH MISTIE Study subject. Their patient had a 31cc basal ganglia ICH and a GCS of 8T at the time of enrollment. The subject was randomized to surgery. During surgery, 16cc of clot was aspirated. The study team is currently awaiting CT scan results post catheter repositioning in order to determine if drug dosing will be necessary or if a successful surgical endpoint has already been reached.

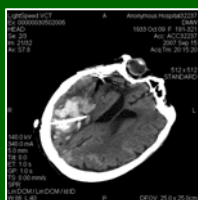
The team at Evanston Northwestern Healthcare is now solely responsible for over 30% of our total study subject enrollments, and is solely responsible for 50% of our total study subject randomizations! You have firmly established yourselves as "the team to beat"!

Congratulations to Dr. Mario Zuccarello, his Research Coordinator (Carolyn Koeng, RN, MS), and the rest of the MISTIE Study research team at the University of Cincinnati in Ohio for enrolling their third subject. Their patient was randomized to the medical treatment arm on August 29, 2007. At that time, the subject had an ICH of approximately 56cc and a GCS of 12. The patient recently has had a GCS of 14 and is receiving further care in the Neuro ICU. Thank you University of Cincinnati!

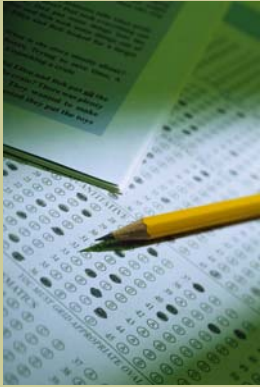
The MISTIE Study team at Evanston Northwestern Healthcare in Evanston, Illinois enrolled their SEVENTH subject on September 12th! This team is unstoppable! Congratulations once again go out to Dr. Issam Awad, his Research Coordinators (Judy O'Leary, RN, OCN, CCRP and Jenny Levin, MPH), and the rest of his MISTIE Study research team. The subject had a 130cc (that is no typo) ICH and a GCS of 12 at enrollment. The subject was randomized to surgery. During surgery, 62cc of clot were aspirated. The subject then received 9 doses of study drug. At that time, the ICH clot size was 27.5cc. Current update: the subject was recently discharged to a regular floor.



Pre-surgery stability scan, Evanston Northwestern's most recent patient (above)



Post-treatment scan, 9 doses given — 4 days post-injury (above)



➔ NIHSS and GCS are important tools for tracking extended patient recovery

➔ Retraining for the NIHSS can be found at [www.nihstrokescale.org](http://www.nihstrokescale.org)

## eCRForum

Recent reviews of follow-up visits have shown needed information is not being collected. Acknowledging the GOS and SIS scoring was not in the initial CRF pack for the 30, 90, and 180 day follow-up, the Coordinating Center would like to express the importance of collecting this data. To help clarify the information needed at the 30, 90, and 180 day follow-up visits, the table on the right is a portion of the Study Timeline from the protocol displaying the necessary scales to be completed for each follow-up visit. If the eGOS and SIS are not collected it is a Protocol Violation and the appropriate form must be filled out. This study is based on outcomes; and without this data we will be unable to make conclusions about the effectiveness of the MISTIE treatment. Please take a moment to review the information that needs to be collected.

	Day 30†	Day 90†	Day 180†
Daily CT Scan	X		X
NIHSS	X		X
Barthel Index	X	X	X
Modified Rankin	X	X	X
Stroke Impact Scale	X	X	X
GOS	X	X	X
eGOS	X	X	X

## No one outcome can describe recovery

The National Institutes of Health Stroke Scale (NIHSS) is specifically designed to assess intervention differences in clinical trials. For clinical research, the NIHSS is more sensitive than other scales and has more power to detect intervention differences in a smaller sample size; because of this, it has become a key measurement tool in thrombolytic studies.

Clinicians now use the NIHSS for triage decision-making and long-term resource planning after stroke. It has become a valuable tool to measure initial neurological deficits in the emergency department and is predictive of long-term outcome. In several studies, two-thirds of patients with a score  $\leq 3$  at day 7 had excellent outcome; whereas very few patients with a score  $\geq 15$  had excellent outcomes at 3 months. Studies show that more than 80% of patients whose score is  $\leq 5$  at admission will be discharged to home, whereas, those with scores between six and 13 will likely be discharged to inpatient rehabilitation and those with  $\geq 14$  scores will need long-term care in skilled nursing facilities.

Although most of us use the Glasgow Coma Scale (GCS) for monitoring neuroworsening, the NIHSS has become a more sensitive tool. Although not validated, a change of 2 points or more has been used in clinical trials as an indication of neuroworsening prompting emergency imaging and treatment. There are some limitations to the NIHSS: patients with brainstem or cerebellar strokes can score low despite disability, and it is not sensitive enough to score a patient's ability to compensate for neurological deficits. However, its role can be powerful working with patients and their families.

The NIHSS is part of the CLEAR and MISTIE screening criteria and outcome analysis. It is important to be consistent and insistent

in performing this impairment scale in the ER, just prior to enrollment and during the follow-up cycles. It allows us to detect a difference due to rt-PA treatment in our small sample size, but only if we complete these examinations every time it is scheduled in the protocol. **Perhaps we can be more resolute and enthusiastic about completing the NIHSS protocol if we keep in mind its sensitivity to neuroworsening, its predictive usefulness in long-term decision-making, and its value as a key measurement tool in both our trials.**

The NIHSS is a powerful tool, not just for research outcome but for monitoring neuroworsening during the acute phase and in having prognostic discussions. No one outcome measure can describe recovery after stroke, which is why we use multiple stroke scales at baseline and through follow-up. We use different stroke scales to measure neurological deficits (NIHSS), loss of the ability to perform daily tasks (Barthel Index), loss of role function at work or home (modified Rankin Scale, GOS, extended GOS), and quality of life (Stroke Impact Scale [SIS]).

High validity and low intraobserver variability in our trials is made possible by standardized annual training. This is very important in multicenter trials.

Send in your annual certificate please. If you need retraining, please go online to the [American Heart Association NIHSS training](http://www.heart.org). It is user-friendly, forgiving if you cannot complete the exercise in one sitting, and best of all, free. We are starting the retraining campaign in September: **October is NIHSS certification month for both CLEAR and MISTIE**; expect our solicitation of your certificate over the next 30 days.