Stroke Clinical Trials at Intermountain Healthcare

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Objectives:
• Describe the active stroke studies at Intermountain Medical Center
• Identify the need for research in stroke care at a comprehensive stroke center
• List inclusion criteria for one active study at Intermountain Medical Center
• Identify who to contact if they have questions about stroke research at Intermountain Medical Center
Trevan Biddulph, RN – Research Manager for Neurosciences Institute at Intermountain Medical Center

No financial interests to disclose; I may talk about off label drug use in the setting of IRB approved clinical trials
Stroke Statistics

Outcomes from current medical treatment

• Stroke is the third leading cause of death in the United States. More than 140,000 people die each year from stroke in the United States.
• Stroke is the leading cause of serious, long-term disability in the United States.
• Each year, approximately 795,000 people suffer a stroke. About 600,000 of these are first attacks, and 185,000 are recurrent attacks.
• Nearly three-quarters of all strokes occur in people over the age of 65. The risk of having a stroke more than doubles each decade after the age of 55.
• Strokes can and do occur at ANY age. Nearly one fourth of strokes occur in people under the age of 65.
• Stroke death rates are higher for African-Americans than for whites, even at younger ages.
• On average, someone in the United States has a stroke every 40 seconds.
• Stroke accounted for about one of every 17 deaths in the United States in 2006. Stroke mortality for 2005 was 137,000.
• Stroke costs the nation $34 billion annually, including the cost of health care services, medications, and lost productivity.

Source: U.S. Centers for Disease Control and Prevention.
Stroke Burden

Is There a Need for More Treatments?

- Stroke is a tremendous burden to health worldwide both in the developed and developing world.
- The ultimate goal of stroke research is to reduce the burden of disease, and clinical trials are the clearest expression of the value of research because their results can directly impact health.
- In a review of stroke trials funded by the US National Institute of Neurological Disorders and Stroke, we found that the overall impact of the trials was dramatically positive and justified the entire research budget of the Institute.
- More creative and systematic approaches to defining the research agenda and enhancing trial methods could substantially accelerate the rate of discovery and increase the impact of those discoveries on public health. To get there, we desperately need more research.

Source: *Stroke*. 2008; 39: 3431-3436 Published online before print September 25, 2008, doi: 10.1161/STROKEAHA.108.525584
Stroke Burden

Is There a Need for More Treatments?

- Researchers found that only 4 percent of the more than 370,000 Medicare patients who suffered a stroke in 2011 were treated with tPA.
- Lead researcher Dr. Opeolu Adeoye said; “Most stroke victims are within reach of the treatment -- they're just not getting it.”
- So few stroke victims receive tPA, since there is such a short time window for the drug to be given -- and so many people do not act on initial stroke symptoms.

--Do we need more options for treatment or ways to extend the tPA treatment window?

Source: Opeolu Adeoye, M.D., associate professor, emergency medicine and neurosurgery, University of Cincinnati College of Medicine; Bruce Ovbiagele, M.D., professor, neurosciences, Medical University of South Carolina, Charleston; Ross Tobleman, M.D., medical director, emergency department, Scott & White Hospital, Round Rock, Texas; Feb. 13, 2014, presentation, American Stroke Association meeting, San Diego
Current Stroke Research at Intermountain

Active and Closed Studies

Ischemic Stroke
- MR WITNESS

Hemorrhagic Stroke
- MISTIE III
- ATACH-II
Current Stroke Research at Intermountain

MR WITNESS: A Phase IIa Safety Study of Intravenous Thrombolysis With Alteplase in MRI-Selected Patients

Purpose:

• This study was jointly developed and is jointly led by investigators at Massachusetts General Hospital and the intramural division of NINDS. We are doing this research study to find out if Activase ® (also called alteplase or rt-PA) can safely be given to people with an acute ischemic stroke when their stroke onset was not witnessed making them ineligible for standard thrombolytic (clot busting) therapy. We also want to find out if rt-PA can help people recover better from their stroke.

• The purpose of this study is to: 1) see if it is safe to give intravenous (IV) rt-PA to people with unwitnessed stroke but with MRI evidence of early ischemic stroke, 2) see if rt-PA is effective if given to people who are selected for treatment based on MRI evidence of an early stroke, and 3) get information about this new MRI diagnostic methods for guiding stroke treatment.

Sponsor:

• Lee Schwamm, MD - Vice Chairman, Department of Neurology and Director, TeleStroke & Acute Stroke Services at Mass General Hospital

Enrollment

• 80 patients from 14 sites located all over the United States
Current Stroke Research at Intermountain

MR WITNESS: A Phase IIa Safety Study of Intravenous Thrombolysis With Alteplase in MRI-Selected Patients

Exclusion Criteria:

• History of intracranial hemorrhage
• Not eligible for tPA based on sites tPA criteria (see tPA check list in stroke packet)
• Oral anticoagulant treatment, regardless of INR.
• Other major disorders associated with an increased risk of bleeding
• Eligible for rt-PA therapy per institutional protocol as part of routine clinical practice
• Non-ischemic etiology demonstrated by neuroimaging
• Neuroimaging (CT or gradient echo MRI) evidence of acute or chronic ICH (non-microbleed)
• Presence of 10 or more microbleeds on GRE (suggestive of amyloid angiopathy)
• Any contraindication for MRI, e.g. presence of a pacemaker, ferromagnetic aneurysm clip, etc, pre-menopausal women with a positive pregnancy blood test, or severe claustrophobia.
• Poor quality MRI- images are not interpretable
• In the opinion of the investigator, the patient is not an appropriate candidate for IV rt-PA
• Women known to be pregnant, lactating or having a positive or indeterminate pregnancy test.
Current Stroke Research at Intermountain

MR WITNESS: A Phase IIa Safety Study of Intravenous Thrombolysis With Alteplase in MRI-Selected Patients

Inclusion Criteria:
• Age, 18 to 85 years inclusive
• Brain MRI findings consistent with early stroke onset
• Clinical diagnosis of acute ischemic stroke with disabling neurological deficit
• Stroke symptoms present for at least 30 minutes with no significant improvement before treatment
• Be last known well (without stroke symptoms) within 24 hours of triage
• Be able to receive IV rt-PA within 4.5 hours from the time the symptoms were discovered.
• MRI diagnostic of acute ischemic stroke and consistent with clinical syndrome
• Time between completion of qualifying MRI studies to treatment initiation ≤ 1 hour
• Pre morbid Modified Rankin Scale of 0 or 1

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Current Stroke Research at Intermountain

**MR WITNESS: A Phase IIa Safety Study of Intravenous Thrombolysis With Alteplase in MRI-Selected Patients**

Impact on Stroke Treatment:

- Approximately 25% of ischemic stroke patients have unwitnessed strokes and 16-28% of stroke patients wake-up with their symptoms.
- These patients are not eligible for thrombolytic treatment based on last known well time or because their symptom onset was beyond the thrombolytic time window. This factor contributes to the low treatment percentage rates of IV rt-PA which was reported as 3 to 8.5% in a recent study of US medical centers.
- A recent retrospective study of wake-up stroke subjects who were treated with compassionate use IV rt-PA using CT suggests that rt-PA may be safely administered in a select population of subjects with wake-up stroke.
- MRI Fluid-Attenuated Inversion Recovery (FLAIR) signal intensity changes over time, this parameter has been proposed as a “tissue clock” when the precise time of symptom onset is unknown. Other research has showed that the positive predictive value for predicting on-set time less than three hours was 94%. Thomalla et al.
Current Stroke Research at Intermountain

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Current Stroke Research at Intermountain

MR WITNESS: A Phase IIa Safety Study of Intravenous Thrombolysis With Alteplase in MRI-Selected Patients

Impact on Stroke Treatment:
• How does this study have to potential to impact stroke treatment?

1. Provide criteria to use MRI to determine an accurate onset time of brain ischemia
2. Allow the possibility of tPA treatment for 16-28% of stroke patients who woke up with symptoms

Results from Phase II expected February 2016
Current Stroke Research at Intermountain

**ATACH-II - Antihypertensive Treatment of Cerebral Hemorrhage**

CLOSED

Primary Hypothesis:

- The primary hypothesis of this large, streamlined, focused trial is that intensive systolic blood pressure (SBP) reduction using intravenous (IV) nicardipine with treatment initiated within three (3) hours of onset of ICH and continued for the next 24 hours reduces the likelihood of death or disability at three (3) months after ICH by ten percent (10%) or greater compared with standard SBP reduction. The underlying mechanism for this expected beneficial effect of intensive treatment is presumably mediated through reduction of the rate and magnitude of hematoma expansion observed in approximately seventy-three percent (73%) of patients with acute ICH.
Current Stroke Research at Intermountain

**ATACH-II - Antihypertensive Treatment of Cerebral Hemorrhage**
CLOSED

Study Design:

- Two groups of patients with hypertension and Intracerebral Hemorrhage were compared.
  - 1st group, Systolic blood pressure kept below 180 mmHg using IV Nicardipine (target SBP of 160 mmHg)
  - 2nd group systolic blood pressure kept below 140 mmHg using IV Nicardipine (target SBP of 125 mmHg)
- Total enrollment 1,280 patients
  - Enrollment closed at 850 patients
- Outcomes compared using post hospital Modified Rankin Score (mRS) between the 2 groups
Current Stroke Research at Intermountain

**ATACH-II - Antihypertensive Treatment of Cerebral Hemorrhage**
CLOSED

Study Interim Results:
- The current data indicate the trial is unlikely to demonstrate a difference in outcomes between the two treatment groups even if it completes the enrollment planned of 1,280 subjects.

What does this mean?
- BP lower than 180 and 140 have essentially the same clinical outcomes
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**MISTIE III** - Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation
Currently Enrolling

**Primary Hypothesis:**
- The MISTIE III intervention seeks to remove blood from the brain through minimally invasive surgery and intermittent dosing of a clot-busting drug, a recombinant tissue plasminogen activator (rt-PA) called alteplase. The study premise is that by removing the blood clot faster, injury to the brain will be reduced and the patient’s long-term prognosis will improve.
- MISTIE III is the result of over 10 years of preliminary research and clinical trials. An earlier study, MISTIE II, was completed in April 2013. That study suggests that this investigational treatment may offer a possible new treatment for this devastating condition. This next study, MISTIE III, was designed to confirm these preliminary findings in a larger number of patients. The hope is that the MISTIE approach can improve patient's long-term quality of life. The primary endpoint is a outcomes assessment called the Modified Rankin Score measured at 180 and 365 days after the stroke.
Current Stroke Research at Intermountain

**MISTIE III - Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation**

Currently Enrolling

**Funding:**
- MISTIE III is funded by the National Institute of Neurological Disorders and Stroke (NINDS), one of the National Institutes of Health (NIH)

**Primary Investigators:**
- The trial is led by Study Chairman and Co-Principal Investigator Dr. Daniel Hanley of Johns Hopkins University and coordinated by the Brain Injury Outcomes service (BIOS) in the Department of Neurology. There are two surgical coordinating centers: University of Chicago, led by Co-Principal Investigator Dr. Issam Awad and the University of Cincinnati lead by Co-Principal Investigator Dr. Mario Zuccarello.
Current Stroke Research at Intermountain

**MISTIE III** - Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation
Currently Enrolling

Inclusion Criteria:

- Spontaneous supratentorial ICH \( \geq 30 \text{ mL} \) diagnosed using radiographic imaging (CT, CTA, etc.), with a GCS \( \leq 14 \) or a NIHSS \( \geq 6 \).
- Six-hour clot size equal to the most previous clot size (within 5 mL) as determined by additional CT scans at least 6 hours apart using the ABC/2 method.
- Symptoms less than 24 hours prior to diagnostic CT (dCT) scan (an unknown time of onset is exclusionary).
- Intention to initiate surgery between 12 and 72 hours after dCT. First dose can be given within 76 hours after dCT (delays for post surgical stabilization of catheter bleeding or because of unanticipated surgical delay are acceptable with approved waiver from the CCC).
- SBP < 180 mmHg sustained for six hours recorded closest to the time of randomization.
- Historical Rankin score of 0 or 1.
- Age \( \geq 18 \) and \( \leq 80 \).
Current Stroke Research at Intermountain

MISTIE III - Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation
Currently Enrolling

Exclusion Criteria:
• Intraventricular hemorrhage requiring treatment with extraventricular drainage (obstruction of third and fourth ventricles).
• Thalamic bleeds with apparent midbrain extension with third nerve palsy or dilated and non-reactive pupils.
• Ruptured aneurysm, arteriovenous malformation (AVM), vascular anomaly, Moyamoya disease diagnosed with radiographic imaging.
• Patients with unstable mass or evolving intracranial compartment syndrome.
• Platelet count < 100,000, INR > 1.4, or an elevated prothrombin time (PT) or activated partial thromboplastin time (aPTT).
• Any irreversible coagulopathy or known clotting disorder.
• Inability to sustain INR ≤ 1.4 using short- and long-active procoagulants (such as but not limited to NovoSeven, FFP, and/or vitamin K).
• Subjects requiring long-term anti-coagulation are excluded. Reversal of anti-coagulation is permitted for medically stable patients who can realistically tolerate the short term risk of reversal. Patient must not require Coumadin (anticoagulation) during the first 30 days, and normalized coagulation parameters must be demonstrated, monitored closely and maintained during the period of brain instrumentation.
• Use of Dabigatran prior to symptom onset.
• Internal bleeding, involving retroperitoneal sites, or the gastrointestinal, genitourinary, or respiratory tracts.
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**MISTIE III - Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation**

Currently Enrolling

**Exclusion Criteria:**

- Superficial or surface bleeding, observed mainly at vascular puncture and access sites (e.g., venous cutdowns, arterial punctures, etc.) or site of recent surgical intervention.
- Positive urine or serum pregnancy test in pre-menopausal female subjects without a documented history of surgical sterilization.
- Allergy/sensitivity to rt-PA.
- Prior enrollment in the study.
- Subjects who are not expected to survive to the day 365 visit due to co-morbidities and/or are DNR/DNI status prior to randomization are excluded.
- Any concurrent serious illness that would interfere with the safety assessments including hepatic, renal, gastroenterologic, respiratory, cardiovascular, endocrinologic, immunologic, and hematologic disease.
- Patients with a mechanical heart valve.
- Known risk for embolization, including history of left heart thrombus, mitral stenosis with atrial fibrillation, acute pericarditis, or subacute bacterial endocarditis.
- Any other condition that the investigator believes would pose a significant hazard to the subject if the investigational therapy were initiated.
- Active drug or alcohol use or dependence that, in the opinion of the site investigator, would interfere with adherence to study requirements.
- In the investigator's opinion, the patient is unstable and would benefit from a specific intervention rather than supportive care plus or minus MIS+rt-PA removal of the ICH.
- Inability or unwillingness of subject or legal guardian/representative to give written informed consent.
Current Stroke Research at Intermountain

**MISTIE III** - *Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation*

Currently Enrolling

Study Design:

- Compare results between traditional medical management for patients with hypertensive Intracerebral Hemorrhage and minimally invasive surgery
- Results from MISTIE Phase II
  - Benefit greater at 365 than 180 days
  - 14% upward shift across mRS levels 5 to 0
  - 14% fewer MIS treated subjects in LTC facilities
  - Shorter hospital stay for MIS treated subjects
  - Estimated acute care cost savings $44,000
  - Procedure is Simple, Rapid and Easy to Generalize
Current Stroke Research at Intermountain

**MISTIE III - Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation**

Currently Enrolling

Impact on care, if the study hypothesis proves to be true:

- A new treatment is available to patients who otherwise would not have a treatment
- Less cost for patients with this type of stroke
- An increase in the likely hood of having a good outcome (mRS 2 or less)
Future Stroke Research at Intermountain

Possible Studies for NETT – Neurological Emergency Treatment Trials

POINT - Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke Trial
• POINT is a randomized, double-blind, multicenter clinical trial to determine whether clopidogrel 75mg/day (after a loading dose of 600mg) is effective in improving survival free from major ischemic vascular events (ischemic stroke, myocardial infarction, and ischemic vascular death) at 90 days when initiated within 12 hours time last known free of new ischemic symptoms of TIA or minor ischemic stroke in subjects receiving aspirin 50-325mg/day

MaRISS – Mild and Rapidly Improving Stroke Study
• The purpose is to evaluate treatment options for patients with mild and rapidly improving stroke symptoms by analyzing data from 100 hospitals participating in the Get With The Guidelines®- Stroke quality program
Future Stroke Research at Intermountain  
*POINT - Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke Trial*

**Study Objectives:**

- POINT is a randomized, double-blind, multicenter clinical trial to determine whether clopidogrel 75 mg/day given orally after a loading dose of 600 mg is effective in reducing the 90-day risk of stroke, myocardial infarction and vascular death (primary composite outcome) when initiated within 12 hours of transient ischemic attack (TIA) or minor ischemic stroke onset in patients also receiving aspirin 50-325 mg/day. Several secondary analyses will be performed, including as treated analysis and evaluations of the impact of therapy on risk of the composite of major ischemic vascular events or major hemorrhage, and on risk of major systemic or intracranial hemorrhage separately. Additional tertiary/exploratory analyses will include evaluation of the impact of therapy on: 1) ischemic stroke, 2) hemorrhagic stroke, 3) all-cause death, and 4) new handicap as measured by a change in the modified Rankin Scale score. The impact of therapy on the composite outcome will also be evaluated in specific patient groups (e.g., African Americans, those previously taking aspirin, those with imaging evidence of new infarction).
Future Stroke Research at Intermountain

**POINT - Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke Trial**

Inclusion Criteria:

• Neurological deficit (based on history or exam) attributed to focal brain ischemia and EITHER:
  • High risk TIA: Complete resolution of the deficit at the time of randomization AND ABCD2 score of (greater than or equal to) 4 OR
  • Minor ischemic stroke: residual deficit with NIHSS of (less than or equal to) 3 at the time of randomization

• Ability to randomize within 12 hours of time last known free of new ischemic symptoms.

• Head CT or MRI ruling out hemorrhage or other pathology, such as vascular malformation, tumor, or abscess, that could explain symptoms or contraindicate therapy.

• Ability to tolerate aspirin at a does of 50-325 mg/day.
Exclusion Criteria:

- Age <18 years
- TIA symptoms limited to isolated numbness, isolated visual changes, or isolated dizziness/vertigo.
- In the judgment of the treating physician, a candidate for thrombolysis, endarterectomy or endovascular intervention, unless the subject declines both endarterectomy and endovascular intervention at the time of evaluation for eligibility.
- Receipt of any intravenous or intra-arterial thrombolysis within 1 week prior to index event.
- Gastrointestinal bleed or major surgery within 3 months prior to index event.
- History of nontraumatic intracranial hemorrhage.
- Clear indication for anticoagulation (e.g., warfarin, heparin) anticipated during the study period (atrial fibrillation, mechanical heart valve, deep venous thrombosis, pulmonary embolism, antiphospholipid antibody syndrome, hypercoagulable state).
- Qualifying ischemic event induced by angiography or surgery.
- Severe non-cardiovascular comorbidity with life expectancy <3 months.
- Contraindication to clopidogrel or aspirin.
Future Stroke Research at Intermountain

**POINT - Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke Trial**

- Severe renal (serum creatinine >2 mg/dL or 176.8umol/L) or hepatic insufficiency (prior or concurrent diagnosis, with International Normalized Ratio (INR)>1.5 or any resultant complication, such as variceal bleeding, encephalopathy, or icterus)
- Hemostatic disorder or systemic bleeding in the past 3 months
- Current thrombocytopenia (platelet count <100 x10^9/l) or neutropenia (<1 x10^9/l)
- History of drug-induced hematologic or hepatic abnormalities
- Anticipated requirement for long-term (>7 day) non-study antiplatelet drugs (eg, dipyridamole, clopidogrel, ticlopidine), or Non-steroidal Anti-inflammatory Drugs (NSAIDs) affecting platelet function (such as prior vascular stent or arthritis).
- Inability to swallow medications.
- At risk for pregnancy: premenopausal or post menopausal woman within 12 months of last menses without a negative pregnancy test or not committing to adequate birth control (e.g., oral contraceptive, two methods of barrier birth control, or abstinence).
- Unavailability for follow-up.
- Signed and dated informed consent not obtained from patient.
- Other neurological conditions that would complicate assessment of outcomes during follow-up.
- Ongoing treatment in another study of an investigational therapy or treatment in such a study within the last 7 days.
- Previously enrolled in the POINT study.
Important Points:

• These patients are not eligible for tPA due to rapidly improving symptoms and strokes that are too mild for treatment.
• Offers a treatment for patients with a high risk of having another TIA or ischemic stroke
Future Stroke Research at Intermountain

MaRISS – Mild and Rapidly Improving Stroke Study

MaRISS – Mild and Rapidly Improving Stroke Study

- Mild and improving stroke symptoms are common, affecting 42% (Smith 2011) to 47% (George 2009) of all patients, and the great majority is not treated with acute recanalization therapy. However, up to one third of these patients are reported to have poor outcomes (Fisher 2010). Currently, there are no large studies that have evaluated long-term outcomes in mild and rapidly improving stroke in a standardized manner.
- Informational study only, but care of these patients will be analyzed to determine if there is one clinical practice that is better than others.
Future Stroke Research at Intermountain

MaRISS – Mild and Rapidly Improving Stroke Study

Inclusion Criteria:

• Patients with mild or rapidly improving acute ischemic stroke defined clinically. MaRISS does not define Mild Stroke or Rapidly Improving Stroke for purposes of enrollment. It enrolls patients after the determination to treat or not to treat has been made, in order not to influence treatment decisions.

• Absence of non-ischemic conditions neuro-imaging (i.e. absence of hemorrhage or a masson non-contrast brain CT, or more advanced imaging obtained according to participating site’s imaging protocol).

• Age 18 years or older.

• Arrival to the hospital within 4.5 hours after the onset of stroke symptoms.

• Willing to provide consent.

• Available by telephone and willing to receive two follow-up telephone calls over the next 3 months.
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MaRISS – Mild and Rapidly Improving Stroke Study

Exclusion Criteria:

• Acute stroke patients arriving to the hospital beyond 4.5 hours from symptom onset.
• Unable to obtain consent from either patient or legally authorized representative.
• Pre-morbid modified Rankin scale greater than 1.
• Not available by telephone.
Stroke Research at Intermountain

- Questions
- Comments
- Thoughts