

# The American Stroke Association 28th International Stroke Conference

February 13 – 15, 2003, Phoenix, Arizona  
www.strokeconference.org



CTP16

## Abciximab and rt-PA in Acute Ischemic Stroke Treatment

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Abciximab and rt-PA in Acute Ischemic Stroke Treatment. PI: Daniel C. Morris, MD. **Purpose:** Treatment of acute ischemic stroke with rt-PA is limited to patients presenting to the Emergency Department within three hours of symptom onset. The risk of symptomatic intracranial hemorrhage (ICH) from treatment with rt-PA has caused great resistance of its clinical use by Emergency Physicians and Neurologists. Preclinical data supports the hypothesis that a combination therapy using rt-PA with abciximab enhances the therapeutic effect of rt-PA and decreases the likelihood of ICH. In addition, preclinical data also indicates that in combination with abciximab, the dose of rt-PA can be reduced and the therapeutic benefit retained. **Design:** Open-label phase I safety study using the combination of a reduced dose of rt-PA and full dose abciximab in acute ischemic stroke. Three rt-PA doses (0.45 mg/kg, 0.60 mg/kg and 0.75 mg/kg) combined with full dose abciximab will be tested. Forty-two patients will be enrolled in three dose cohorts with 14 patients in each group. The study will begin with the lowest rt-PA dose (0.45 mg/kg). If no ICHs are observed, then the rt-PA dose will be escalated. The primary outcome measurement in this safety study is ICH. Secondary outcome measures include the NIH stroke scale (NIHSS) score, modified Rankin score, Barthel index and Glasgow Outcome Score at 24 hours and at hospital discharge.

**Results:** The study began on September 3, 2002 and two patients have been enrolled with NIHSS scores of 16 and 20. No ICHs were observed 24 hours after treatment in either patient. At hospital discharge, each patient suffered no bleeding complications and the discharge NIHSS score of each patient was 10. **Conclusion:** Administration of both rt-PA and abciximab is feasible and enrollment is ongoing