**Purpose:** To determine if infarct size in acute ischemic stroke (AIS) is reduced by an intravenous (IV) dose of natalizumab, (an anti-inflammatory antibody used in multiple sclerosis).

**Trial Design:** Phase 2. Randomized, double-blinded, placebo-controlled, parallel-group (1:1) safety/efficacy, proof-of-concept study. 90 day f/u. N= 159. Patients with AIS were given one dose of natalizumab 300 mg IV or placebo within 9 hours from when they were last known to be normal.

**Primary Endpoint:** Infarct volume change (measured by MRI) from baseline to day 5.

<table>
<thead>
<tr>
<th>Trial Results</th>
<th>Day 5</th>
<th>P value</th>
<th>Day 30</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative Infarct Growth Ratio</td>
<td>1.09</td>
<td>0.779</td>
<td>1.05</td>
<td>0.684</td>
</tr>
</tbody>
</table>

**Clinical Results** (secondary endpoint)
- mRS ≤1 out of 0-6: day 30: OR=2.88; day 90: OR= 1.48
- Death: natalizumab 18% vs. placebo 16%
- Serious adverse events: natalizumab 46% vs. placebo 46%

**Conclusions:** Compared to the placebo results, growth of the infarct volume was not less with natalizumab. Clinical outcomes appeared to be better for the natalizumab patients.