Primary Results of the ACTION Trial of Natalizumab in Acute Ischemic Stroke (AIS)

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.

Trial Results	Day 5	P value	Day 30	P value
Relative Infarct Growth Ratio	1.09	0.779	1.05	0.684

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.

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