

Results of the DEFUSE 3 Study



Purpose: To determine if disability is reduced with an expanded treatment window (6-16 hours) for mechanical thrombectomy in patients with large vessel blockage in the anterior circulation who have a favorable imaging profile (salvageable tissue) identified with computed tomography perfusion or magnetic resonance diffusion/perfusion.

Trial Design: Phase 3, prospective, controlled, multicenter (38), blinded, randomized 1:1 6-16 hours of onset of symptoms to endovascular therapy + medical management vs medical management. N=182. Automated software (RAPID) analyzed the blood flow to detect slowly expanding changes. NIH-NINDS StrokeNet trials group funding.

Primary Endpoints: modified Rankin scale score distribution at 90 days

90-day Rankin scale	Endovascular + medical management vs. Medical Management
Improvement in functional outcomes	OR 2.77, $p < 0.001$
Functionally independent	45% vs 17%, $p < 0.001$
Mortality rate	14% vs. 26%, $p = 0.05$
Symptomatic intracranial hemorrhage	7% vs 4%, $p = 0.75$
Serious adverse events	43% vs. 53%, $p = 0.18$

The study was stopped early because of a high probability of benefit in the endovascular + medical management arm. Endovascular + medical therapy vs. medical therapy avoided disability in almost 50% of these AIS study patients treated in the 6-16 hour time window.