

RANDOMIZED TRIALS FOR STANDARD RISK/HIGH-RISK POPULATION (SYMPTOM STATUS: SYMPTOMATIC/MIXED)



Name (Source)	Surgical Risk	Symptom Status	Primary Endpoint	30-Day All Stroke/Death		30-Day All Stroke ^a		30-Day Major/Disabling Stroke ^a			30-Day Death ^a		30-Day Stroke/Death Ratio		MI Routinely Surveyed (Y/N)	30-Day Myocardial Infarction (MI) ^a		EPD Use (%)	Status
				CAS	CEA	CAS	CEA	CAS	CEA		CAS	CEA	CAS	CEA		CAS	CEA		
EVA-3S (NEJM. 2006;355:1660-1771)	Standard	Symptomatic	Incidence of any stroke or death within 30 days after treatment	25 (9.6%)	10 (3.9%)	23 (8.8%)	7 (2.7%)	7 (2.7%)	1 (0.4%)		0.8%	2 (1.2%)	23:2 = 11.5	7.2:2.3 = 2.3	N	1 (0.4%)	2 (0.8%)	91.9%	Stopped prematurely (safety)
SPACE (Lancet Neuro. 2008;7:893-902)	Standard	Symptomatic	Ipsilateral stroke (either ischemic stroke or intracerebral hemorrhage, with symptoms that lasted for more than 24 hours) or death of any cause between randomization and 30 days after treatment	45 (7.4%) ITT; 42 (7.3%) per protocol	39 (6.6%) ITT; 32 (5.7%) per protocol	44 (7.2%) ITT; 41 (7.2%) per protocol	37 (6.3%) ITT; 31 (5.5%) per protocol	25 (4.1%) ITT; 24 (4.2%) per protocol	17 (2.9%) ITT; 14 (2.5%) per protocol		6 (1%) ITT; 4 (1%) per protocol	5 (1%) ITT; 3 (1%) per protocol	44:6 = 7.3	37:5 = 7.4	N	N/A	N/A	Optional distal embolic protection used in 27%	Stopped prematurely (funding)
ICSS (Lancet. 2010;375:985-997) ^b	Standard	Symptomatic	Difference between groups in long-term rate of fatal or disabling stroke in any territory	72 (8.5%)	40 (4.7%)	65 (7.7%)	35 (5.2%)	17/853	20/857		19 (2.3%)	7 (0.8%)	65:19 = 3.4	35:7 = 5	N	4 (0.5%)	3 (0.4%)	72% (Recommended but not mandatory)	Completed
CREST (NEJM. 2010;363:11-23)	Standard	Symptomatic	Stroke, MI, or death from any cause during the periprocedural period or any ipsilateral stroke within 4 years of randomization	40 (6%)	21 (3.2%)	37 (5.5%)	21 (3.2%)	11 (0.9%)	8 (0.6%)		9 (0.7%)	4 (0.3%)	52:9 = 5.8	29:4 = 7.3	Y	7 (1%)	15 (2.3%)	96.1%	Completed
		Asymptomatic		15 (2.5%)	8 (1.4%)	15 (2.5%)	8 (1.4%)										7 (1.2%)		
SAPPHIRE (NEJM. 2004;351:1493-1501)	High	Mixed (Results not published for symptom status)	Stroke, death, or MI at 30 days plus ipsilateral stroke or death from neurologic causes within 31 days to 1 year	Death, stroke, or MI: 8 (4.8%) ITT; 7 (4.4%) actual	Death, stroke, or MI: 16 (9.8%) ITT; 15 (9.9%) actual	6 (3.6%) ITT; 5 (3.1%) actual	5 (3.1%) ITT; 5 (3.3%) actual	Major ipsilateral: 1 (0.6%) ITT; 0 actual	Major ipsilateral: 2 (1.2%) ITT; 2 (1.3%) actual		2 (1.2%) ITT; 1 (0.6%) actual	4 (2.5%) ITT; 3 (2%) actual	6:2 = 3	5:4 = 1.25	Y	4 (2.4%) ITT; 3 (1.9%) actual	10 (6.1%) ITT; 10 (6.6%) actual	95.6%	Stopped prematurely (recruitment)

^aNonhierarchical.

^bInterim analysis (120 days).

ITT, intention to treat.