RANDOMIZED TRIALS FOR STANDARD-RISK POPULATION (SYMPTOM STATUS: ASYMPTOMATIC)

Endovascular TODAY

Name (Source)	Sponsor	Sample Size	Statistical Design			Operator Entry Requirements	Stent	EPD	Primary Endpoint	Status
			Noninferiority/ Superiority	Randomization Protocol						
ACT I (http://clinicaltrials.gov/ct2/show/NCT00106938)	Abbott Vascular	1,658	To demonstrate the noninferiority of CAS using the Emboshield and Emboshield Pro embolic protection systems with the Xact carotid stent system to CEA for the treatment of asymptomatic extracranial carotid atherosclerotic disease	3:1; CAS vs CEA		Rigorous screening of case logs and individual operator experience by Surgical Management and Interventional Management committees made up of expert surgeons and interventionists.	Xact carotid stent	Emboshield and Emboshield Pro	Composite of any stroke, MI, or death during a 30-day postprocedural period, and ipsilateral stroke between 31 and 365 days postprocedure	Recruiting
ACST 2 (http://clinicaltrials.gov/ct2/show/NCT00883402)	St George's, University of London/University of Oxford	At least 5,000 patients with asymptomatic carotid stenosis in whom intervention is thought to be needed but where there is substantial uncertainty about the appropriate choice of treatment	To compare CEA with CAS in the prevention of stroke in patients with asymptomatic carotid stenosis (superiority trial)	1:1; CAS vs CEA		Vascular surgeons should have had a reasonable amount of successful experience with the procedure. Interventionists who may perform CAS should have had a reasonable amount of experience with up-to-date techniques of stenting. In general (except for any cases where there were special reasons for technical failure), collaborators should have ≤ 8% stroke and death risk for symptomatic patients and ≤ 4% stroke and death risk for asymptomatic patients, as in previous major trials, or some appropriate combination of these percentages. The minimum requirement is 25 nonproctored cases in the last 2 years (median CAS experience is currently 62 cases).	N/A	N/A	To compare periprocedural risks (MI, stroke, and death within the first month after the allocated CEA or CAS as attempted by an experienced practitioner), and long-term (up to 5 or more years) prevention of stroke, particularly disabling or fatal stroke, in subsequent years	Recruiting
SPACE 2 (Int J Stroke. 2009;4:294-299; http://www.strokecenter.org/trials/TrialDetail.aspx?tid=950)	German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)	3,640	To demonstrate superiority of stent-protected angioplasty or CEA as compared to best medical treatment with respect to the composite primary endpoint; stent-protected angioplasty is not inferior to CEA with respect to the composite primary endpoint	1:1:1; CAS vs CEA vs BMT		At each study center at least a neurologist, a vascular surgeon, and an interventionist must exist. Neurologists must show expertise in carotid duplex and experience in the treatment of stroke patients. Vascular surgeons required performance of ≥ 40 successful operations on the carotid artery in the previous 2 years and participation in a quality assurance program. Interventionists required performance of ≥ 10 interventions in the context of SPACE-1 with complications < 7% or performance of ≥ 40 stents for severe carotid artery stenosis within the previous 2 years with independent neurological review and participation in a quality assurance program.	N/A	N/A	Primary outcome is the cumulative rate of events consisting of any stroke within 30 days of treatment; death from any cause within 30 days; ipsilateral ischemic stroke within 5 years	Recruiting
TACIT/CREST 2	N/A	N/A	Unknown	1:1:1; CAS vs CEA vs BMT		N/A	N/A	N/A	N/A	Unfunded