CAS CLINICAL TRIAL UPDATE

Study	Sponsor	Sample Size	Stent	Embolic Protection Device	Lesion Location	Study Design
ACT I	Abbott Vascular	n=1,658	Xact Carotid Stent	EmboShield Embolic Protection System	Extracranial ICA	Randomized multicenter trial for asymptomatic, CEA-eligible patients
ARCHeR 1 & 2	Abbott Vascular	n=436	OTW Acculink	ARCHeR 1: n/a; ARCHeR 2: OTW Accunet	ICA	High-risk registry
ARCHeR 3	Abbott Vascular	n=145	RX Acculink	RX Accunet	ICA	High-risk registry
BEACH	Boston Scientific Corporation	n=747	Carotid Wallstent Monorail Endoprosthesis	FilterWire EX and EZ	ICA/CCA and carotid bifurcation	High-risk registry
CABERNET	EndoTex	n=488	NexStent Carotid Stent	FilterWire EX and EZ	ICA/CCA and carotid bifurcation	High-risk registry
CARES	Cordis Endovascular	n=2,200	Precise RX	AngioGuard RX	ICA/CCA	Multicenter, non-high-risk, pivotal study
CASES Postmarket Surveillance	Cordis Endovascular	n=1,500	Precise	AngioGuard-XP	ICA/CCA	Multicenter, high-risk, post-marketing surveillance study
CREATE	ev3	n=420	Protégé GPS and Protégé RX	Spider OTW	ICA/CCA	High-risk registry
CREATE II	ev3	n=160	Acculink	SpideRX	ICA/CCA	High-risk registry
CAPTURE	Abbott Vascular	n=1,500	RX Acculink	RX Accunet	n/a	Multicenter, postapproval study with sequential enrollment of all patients receiving the Acculink
EMPiRE	Gore & Associates	n=320	Any FDA-approved carotid stent	Gore Neuro Protection System	ICA/CCA and carotid bifurcation	High-risk registry
EPIC US Feasibility	Lumen Biomedical	n=30	Acculink	FiberNet	ICA/CCA and bifurcation	Multicenter, prospective feasibility in high-risk patients
EPIC EU	Lumen Biomedical	n=50	Any approved carotid stent	FiberNet	ICA/CCA and bifurcation	Multicenter prospective study
EXACT	Abbott Vascular	n=1,500	Xact carotid stent	EmboShield Embolic Protection System	Between the origin of the common carotid artery and the intracranial segment of the internal carotid artery	Postapproval study of patients at high risk for CEA
MAVErIC Int'l	Medtronic	n=51	Exponent	Interceptor	ICA/CCA	Outside US high-risk registry
MAVErIC I & II	Medtronic	n=99 (phase I) n=399 (phase II)	Exponent	GuardWire	ICA/CCA	High-risk registry
MAVErIC III	Medtronic	n=413	Exponent	Interceptor Plus	ICA/CCA	High-risk registry
MO.MA	Invatec	n=157	Any	MO.MA	ICA and carotid bifurcation	Multicenter EU registry (75% of final population was high risk)
PRIAMUS	Invatec	n=416	Any	MO.MA	ICA and carotid bifurcation	Multicenter Italian registry (63.5% symptomatic patients)
PASCAL	Medtronic	n=113	Exponent	Any CE Mark-approved device	ICA/CCA	Outside US high-risk registry
SAPPHIRE	Cordis Endovascular	n=724*	Precise (5.5 F, 6 F)	AngioGuard-XP	ICA/CCA	Randomized (CEA and CAS) multicenter trial of high-risk patients; evaluated by multidisciplinary team
TACIT	n/a	n=2,400	Not specified	Not specified	ICA/CCA	Randomized (CAS and medical therapy) multicenter trial
To be determined	Kensey Nash Corp	n=306	Any FDA-approved carotid stent	TriActiv ProGuard System	ICA/CCA	High-risk registry
VIVA	Bard Peripheral Vascular	n=400	Vivexx	Industry partner	ICA/CCA	High-risk registry

		Target Vessel Size (mm)	Results	Status
		Stent: 4.5 to 9.1; EPD segment: 3.5 to 6	n/a	Enrolling
		Stent: 4 to 9 EPD segment: 3.25 to 7	Final 1-y data (all death, stroke, MI within 30 d + all ipsilateral stroke from 31 d to 1 y), ARCHeR 1=8.3%; ARCHeR 2=10.2%; weighted historical control=14.5%	FDA approval received 8/31/04
		Stent: 4 to 9 EPD segment: 3.25 to 7	Final 30-d data (all death, stroke, MI)=8.3%	FDA approval received 8/31/04
		Stent: 4 to 9 EPD segment: 3.5 to 5.5	1-y results (non Q-wave MI: 0-24 h; stroke, death, Q-wave MI: 0-30 d; ipsilateral stroke, neurologic death: 31-360 d): 9.1%	Enrollment complete; 1-y results presented at All That Jazz 2005; currently in long-term follow-up period
		Stent: 4 to 9 EPD segment: 3.5 to 5.5	Primary endpoint 1: 1-y results (all death, stroke, MI 0-30 d + ipsilateral stroke and any death related to ipsilateral stroke 31-365 d): 4.7% Primary endpoint 2: 1-y results (all death, stroke, MI 0-365 d): 11.9%	Enrollment complete; 1-y results presented at PCR 2005; currently in long-term follow-up period
		Stent: 4 to 9.5 EPD segment: 3.5 to 7.4	n/a pending publication	IDE pending approval
		Stent: 4 to 9.5 EPD segment: 3.5 to 7.5	n/a pending publication	Completed; results to be published
		Stent: 4.5 to 9.5 EPD segment: 3 to 7	30-d MACCE: 6.3%	Enrollment complete; 1-y results presented at TCT 2005; 30-d data published July 2006 in JACC
		Stent: 3.6 to 9.1 EPD segment: 3 to 7	30-d MACCE: 5.6%	Enrollment complete; 30-d results presented at TCT 2005; SpiderRX commercially available
		Stent: 4 to 9.1 EPD segment: 3.25 to 7	n/a	Enrolling
		Stent: 4 to 9	n/a	Enrolling
		EPD segment: 2.5 to 7	n/a	Enrolling
		EPD segment: 2.5 to 7	n/a	Enrolling
		Stent: 4.5 to 9.1 EPD segment: 3.5 to 6	n/a	Enrolling
		Stent: 5.5 to 9.5	30-d results: MAE=5.9%	CE Mark approved
		Stent: 5.5 to 9.5	30-d phase I and II pooled results: MAE=5.4%	Enrollment completed
		Stent: 5.5 to 9.5	n/a	Active
f		Mean ICA reference diameter: 6.28	30-d all MACE=5.7%	Completed
		Mean diameter stenosis: 80%±9.8	30-d all stroke and deaths=4.5%; 30-d MI=0%	Completed
		Stent: 5.5 to 9.5	30-d results: MAE=8%	Enrollment completed
		Stent: 4 to 9.5 EPD segment: 3.5 to 7.5	Key Randomized Results: 30-d results for treated patients: 4.4% total MAE, 0.0% major stroke rate; 1-y results: stent patients: death/stroke/MI rate=12%, surgical patients: death/stroke/MI rate=19.2%; precise lesion success <30%=99.4%, AngioGuard XP success rate=98.1%; 2-y results: TLR=1.4%	Trial completed; 3-y results pending publication
l		Stenosis >60%	n/a	Enrolling
		Stent: 4 to 9 EPD segment: 3 to 6	n/a	Trial enrollment begins in October 2006
		Stent: 3.5 to 11	n/a	Enrolling