CAS CLINICAL TRIAL UPDATE

This issue contains articles that detail the current status of the ACST (page 63), CREST (page 55), and TACIT (page 49) trials.

Study	Sponsor	Sample Size	Stent	Embolic Protection Device	Lesion Location	Study Design		Target Vessel Size (mm)	Results	Status
ACT I	Abbott Vascular Devices	n=1,540	Xact Carotid Stent	EmboShield	ICA/CCA	Randomized (CEA and CAS) multicenter trial for asymptomatic subjects at standard risk for CEA		Stent: 4 to 9 EPD segment: 3.5 to 6	N/A	Enrolling
ARCHeR 1 & 2	Guidant	n=436	OTW Acculink	ARCHeR 1: N/A; ARCHeR 2: OTW Accunet	ICA and carotid bifurcation	High-risk registry		Stent: 4 to 9 EPD segment: 3.25 to 7	Final 1-year data (all death, stroke, MI within 30 days + all ipsilateral stroke from 31 days to 1 year), ARCHeR 1=8.3%; ARCHeR 2=10.2%; weighted historical control=14.5%	FDA approval received 8/31/04
ARCHeR 3	Guidant	n=145	RX Acculink	RX Accunet	ICA and carotid bifurcation	High-risk registry		Stent: 4 to 9 EPD segment: 3.25 to 7	Final 30-day data (all death, stroke, MI)=8.3%	FDA approval received 8/31/04
BEACH	Boston Scientific	n=480	Carotid Wallstent Monorail Endoprosthesis	FilterWire EX and EZ	ICA/CCA and carotid bifurcation	High-risk registry		Stent: 4 to 9 EPD segment: 3.5 to 5.5	1 year results (non Q-wave MI: 0-24 hrs; stroke, death, Q-wave MI: 0-30 days; ipsilateral stroke, neurological death: 31-360 days): 9.1%	Enrollment complete. 1-year results presented at All That Jazz 2005; currently in long-term follow-up period
CABERNET	EndoTex	n=488	NexStent Monorail	FilterWire EX and EZ	ICA/CCA and carotid bifurcation	High-risk registry		Stent: 4 to 9 EPD segment: 3.5 to 5.5	Primary endpoint 1: 1-year results (all death, stroke, MI 0-30 days + ipsilateral stroke and any death related to ipsilateral stroke 31-365 days): 4.5% Primary endpoint 2: 1-year results (all death, stroke, MI 0-365 days): 11.5%	Enrollment complete. 1-year results presented at PCR 2005; currently in long-term follow-up period
CASES	Cordis	n=1,500	Precise	AngioGuard-XP	ICA/CCA	Multicenter, high-risk, post-marketing surveillance study		Stent: 4 to 9.5 EPD segment: 3.5 to 7.5	N/A	Enrolling
CREATE	ev3	n=419	Protégé	SPIDER OTW	ICA/CCA	High-risk registry		Stent: 4.5 to 9.5 EPD segment: 3 to 7	30-day MACCE: 6.2%	Enrollment complete 1 year at TCT 2005
CREATE II	ev3	n=160	Guidant Acculink	SpideRX	ICA/CCA	High-risk registry		Stent: 4.5 to 9 EPD segment: 4 to 7	N/A	Enrollment complete
CREST	NIH and Guidant	n=2,500	RX Acculink	RX Accunet	ICA and carotid bifurcation	Randomized multicenter trial for asymptomatic and symptomatic, CEA-eligible patients		Stent: 4 to 9.1 EPD segment: 3.25 to 7	Preliminary results of 30-day stroke and death (<80 year old lead in patients only): asymptomatic = 3.0%; symptomatic = 2.7%	Enrolling
CAPTURE	Guidant	n=1,500	RX Acculink	RX Accunet	N/A	Multicenter, postapproval study that includes sequential enrollment of all patients receiving the ACCULINK Carotid Stent		Stent: 4 to 9.1 EPD segment: 3.25 to 7	N/A	Enrolling
MAVErIC International	Medtronic	n=51	Exponent	Interceptor	ICA/CCA	Outside US high-risk registry		Stent: 5.5 to 9.5	30-day results: MAE=5.9%	CE Mark approved
MAVErIC I & II	Medtronic	n=99 (Phase 1) n=399 (Phase 2)	Exponent	GuardWire	ICA/CCA	High-risk registry		Stent: 5.5 to 9.5	30-day phase 1 and 2 pooled results: MAE=5.4%	Enrollment completed
MAVErIC III	Medtronic	n=413	Exponent	Interceptor PLUS	ICA/CCA	High-risk registry		N/A	N/A	Enrolling
MO.MA	Invatec	n=157	Any	MO.MA	ICA and carotid bifurcation	Multicenter EU Registry (75% of the final population was at high risk)		Mean ICA reference diameter: 6.28	30-day all stroke and deaths=5.7%; 30-day MI=0%	Completed
PRIAMUS	Invatec	n=416	Any	MO.MA	ICA and carotid bifurcation	Multicenter Italian Registry (63.5% symptomatic patients)		Mean diameter stenosis: 80%±9.8	30-day all stroke and deaths=4.5%; 30-day MI=0%	Completed
PASCAL	Medtronic	n=113	Exponent	Any CE Mark-approved device	ICA/CCA	Outside US high-risk registry		Stent: 5.5 to 9.5	30-day results: MAE=8.0%	Enrollment completed
RULE-Carotid	Rubicon Medical	n=60	Any	Rubicon Filter	ICA/CCA	Multicenter EU symptomatic/asymptomiatic registry		EPD segment: 3 to 6	Major adverse events at 30 days = 5%; major stroke/death = 1.6%	CE Mark approved
SAPPHIRE	Cordis	n=724*	Precise (5.5, 6 F)	AngioGuard-XP	ICA/CCA	Randomized (CEA and CAS) multicenter trial of high-risk patients; evaluated by multidisciplinary team		Stent: 4 to 9.5 EPD segment: 3.5 to 7.5	Key randomized results; 30 day results for treated patients: 4.4% total MAE; 0.0% major stroke rate; 1-year 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-year results: TLR=1.4%	Trial completed. 3-year results to be presented at TCT 2005
SECuRITY	Abbott Vascular Devices	n=398	Xact Carotid Stent	EmboShield	ICA/CCA	High-risk registry		Stent: 4 to 9 EPD segment: 3.5 to 6	N/A	1-year results presented at TCT 2004
TACIT	N/A	n=2,400	N/A	N/A	ICA/CCA	Randomized, three-arm, prospective, clinical trial		N/A	N/A	Enrollment anticipated to begin in 2006
VIVA	Bard Peripheral Vascular	n=400	Vivexx Carotid Stent	Industry Partner	ICA/CCA	High-risk registry		Stent: 3.5 to 11	N/A	IDE conditionally approved Trial enrollment begins in October

*Randomized n=310; Stent Registry (Surgical Refusal)=407; Surgical Registry (Stent Refusal)=7