

# Clinical trials of carotid artery stenting

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 carotid stenosis

Trial	Treatments	Patients	Trials design and methods
<b>carotid artery stenting vs medical treatment</b>			
<b>SAMMPRIS , 2011</b> [NCT00576693] n=224/227 follow-up: 11.9 months	aggressive medical management plus percutaneous transluminal angioplasty and stenting versus aggressive medical management alone	patients who had a recent transient ischemic attack or stroke attributed to stenosis of 70 to 99% of the diameter of a major intracranial artery	Parallel groups open
<b>carotid artery stenting vs surgery</b>			
<b>Leicester (Naylor) , 1998</b> n=11/12 follow-up: 65279;1 month	Self-expanding Wallstent versus surgery	patients with focal carotid territory symptoms and severe ICA stenosis (>70% )	Parallel groups open
<b>WALLSTENT (Alberts) , 2001</b> n=107/112 follow-up: 12 months	-	-	Parallel groups open
<b>CAVATAS-CEA , 2001</b> [ISRCTN01425573] n=251/253 follow-up: 36 months (4y)	Pre-1994: PTA only after 1994: Wallstent, Streker, Palmaz versus carotid endarterectomy	patients of any age with symptomatic or asymptomatic carotid artery stenosis suitable for surgery	Parallel groups open
<b>Kentucky A (Brooks) , 2001</b> n=53/51 follow-up: 48 months	Wallstent versus surgery	patients presenting with cerebrovascular ischemia ipsilateral to carotid stenosis	Parallel groups open
<b>Kentucky B (Brooks) , 2004</b> n=43/42 follow-up: 48 months	Wallstent, Dynalink versus carotid endarterectomy	patients with asymptomatic carotid stenosis of more than 80% were selected	Parallel groups open
<b>SAPPHIRE (yadav) , 2004</b> n=167/167 follow-up: 36 months	Smart or Precise (self-expanding nitinol stent)age/pj versus surgery	patients with coexisting conditions that potentially increased the risk posed by endarterectomy and who had either a symptomatic carotid-artery stenosis of at least 50 percent of the luminal diameter or an asymptomatic stenosis of at least 80 percent	Parallel groups open

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>EVA-3S (Mas) , 2000</b> n=261/259 follow-up: 6 months	various stent versus endarterectomy	patients with a symptomatic carotid stenosis of at least 60%	Parallel groups open
<b>SPACE , 2000</b> n=607/589 follow-up: 1 month	carotid-artery stenting (Carotid Wallstent; Precise; Acculink) versus Carotid endarterectomy	patients with symptomatic carotid-artery stenosis within 180 days of transient ischaemic attack or moderate stroke (modified Rankin scale score of <or =3)	Parallel groups open
<b>TESCAS-C (Ling) , 2006</b> n=NA follow-up: 6 months	-	-	Parallel groups open
<b>BACASS (Hoffman) , 2006</b> n=NA follow-up: 45 months	stent versus CEA	patients with symptomatic carotid stenosis >70%	Parallel groups open
<b>Steinbauer , 2008</b> n=43/44 follow-up: 65 months	carotid artery stenting versus Carotid endarterectomy	-	Parallel groups
<b>ICSS , 2010</b> [ISRCTN25337470] n=855/858 follow-up: 120 days	carotid artery stenting versus endarterectomy	patients with symptomatic carotid stenosis of greater than 50% within last six months	Parallel groups open Europe, Australia, New Zealand, Canada
<b>CREST , 2010</b> [NCT00004732] n=2502 follow-up: 2.5y	carotid artery stenting (with distal-protection) versus carotid endarterectomy	patients with both asymptomatic and symptomatic extracranial carotid stenosis	Parallel groups open US, Canada
<b>SPACE 2</b> <i>ongoing</i> n=NA	-	-	
<b>ACST-2</b> <i>ongoing</i> [NCT00883402] n=NA follow-up: 10 years	Carotid Artery Stenting versus Carotid endarterectomy	patients with asymptomatic carotid artery narrowing in whom prompt physical intervention is thought to be needed, but there there is still substantial uncertainty shared by patient and doctor about whether surgery or stenting is the more appropriate choice	Parallel groups open
<b>ACT I</b> <i>ongoing</i> [NCT00106938] n=NA follow-up:	-	-	
<b>Agostoni</b> <i>ongoing</i> n=NA	-	-	

continued...

Trial	Treatments	Patients	Trials design and methods
<a href="#">Link</a> <i>ongoing</i> n=NA	-	-	

More details and results :

- endovascular treatment for carotid stenosis in all type of stenosis at <http://www.trialresultscenter.org/go-Q164>

## References

### **SAMMPRIS, 2011:**

Chimowitz MI, Lynn MJ, Derdeyn CP, Turan TN, Fiorella D, Lane BF, Janis LS, Lutsep HL, Barnwell SL, Waters MF, Hoh BL, Hourihane JM, Levy EI, Alexandrov AV, Harrigan MR, Chiu D, Klucznik RP, Clark JM, McDougall CG, Johnson MD, Pride GL, Torbey MT, Zaidat Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis. *N Engl J Med* 2011 Sep 7;: [21899409] [10.1056/NEJMoa1105335](https://doi.org/10.1056/NEJMoa1105335)

### **Leicester (Naylor), 1998:**

Naylor AR, Bolia A, Abbott RJ, Pye IF, Smith J, Lennard N, Lloyd AJ, London NJ, Bell PR Randomized study of carotid angioplasty and stenting versus carotid endarterectomy: a stopped trial. *J Vasc Surg* 1998;28:326-34 [9719328]

### **WALLSTENT (Alberts), 2001:**

Alberts MJ Results of a multicentre prospective randomized trial of carotid artery stenting vs carotid endarterectomy [ABSTRACT] *Stroke* 2001;32:325.

### **CAVATAS-CEA, 2001:**

Endovascular versus surgical treatment in patients with carotid stenosis in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS): a randomised trial. *Lancet* 2001;357:1729-37 [11403808]

Ederle J, Bonati LH, Dobson J, Featherstone RL, Gaines PA, Beard JD, Venables GS, Markus HS, Clifton A, Sandercock P, Brown MM Endovascular treatment with angioplasty or stenting versus endarterectomy in patients with carotid artery stenosis in the Carotid And Vertebral Artery Transluminal Angioplasty Study (CAVATAS): long-term follow-up of a randomised trial. *Lancet Neurol* 2009 Aug 28;: [19717345]

Bonati LH, Ederle J, McCabe DJ, Dobson J, Featherstone RL, Gaines PA, Beard JD, Venables GS, Markus HS, Clifton A, Sandercock P, Brown MM Long-term risk of carotid restenosis in patients randomly assigned to endovascular treatment or endarterectomy in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS): long-term follow-up of a randomised trial. *Lancet Neurol* 2009 Aug 28;: [19717347]

### **Kentucky A (Brooks), 2001:**

Brooks WH, McClure RR, Jones MR, Coleman TC, Breathitt L Carotid angioplasty and stenting versus carotid endarterectomy: randomized trial in a community hospital. *J Am Coll Cardiol* 2001;38:1589-95 [11704367]

### **Kentucky B (Brooks), 2004:**

Brooks WH, McClure RR, Jones MR, Coleman TL, Breathitt L Carotid angioplasty and stenting versus carotid endarterectomy for treatment of asymptomatic carotid stenosis: a randomized trial in a community hospital. *Neurosurgery* 2004;54:318-24; discussion 324-5 [14744277]

### **SAPPHIRE (yadav), 2004:**

Yadav JS, Wholey MH, Kuntz RE, Fayad P, Katzen BT, Mishkel GJ, Bajwa TK, Whitlow P, Strickman NE, Jaff MR, Popma JJ, Snead DB, Cutlip DE, Firth BG, Ouriel K Protected carotid-artery stenting versus endarterectomy in high-risk patients. *N Engl J Med* 2004;351:1493-501 [15470212]

Gurm HS, Yadav JS, Fayad P, Katzen BT, Mishkel GJ, Bajwa TK, Ansel G, Strickman NE, Wang H, Cohen SA, Massaro JM, Cutlip DE Long-term results of carotid stenting versus endarterectomy in high-risk patients. *N Engl J Med* 2008 Apr 10;358:1572-9 [[18403765](#)]

#### **EVA-3S (Mas), 2000:**

Mas JL, Chatellier G, Beyssen B, Branchereau A, Moulin T, Becquemin JP, Larrue V, Livre M, Leys D, Bonneville JF, Watelet J, Pruvo JP, Albucher JF, Viguier A, Piquet P, Garnier P, Viader F, Touz E, Giroud M, Hosseini H, Pillet JC, Favrole P, Neau JP, Du Endarterectomy versus stenting in patients with symptomatic severe carotid stenosis. *N Engl J Med* 2006;355:1660-71 [[17050890](#)]

Mas JL, Trinquart L, Leys D, Albucher JF, Rousseau H, Viguier A, Bossavy JP, Denis B, Piquet P, Garnier P, Viader F, Touz E, Julia P, Giroud M, Krause D, Hosseini H, Becquemin JP, Hinzelin G, Houdart E, Hnon H, Neau JP, Bracard S, Onnient Y, Padovani R, Endarterectomy Versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) trial: results up to 4 years from a randomised, multicentre trial. *Lancet Neurol* 2008;7:885-92 [[18774745](#)]

#### **SPACE, 2000:**

Ringleb PA, Allenberg J, Brckmann H, Eckstein HH, Fraedrich G, Hartmann M, Hennerici M, Jansen O, Klein G, Kunze A, Marx P, Niederkorn K, Schmiedt W, Solymosi L, Stingele R, Zeumer H, Hacke W 30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomised non-inferiority trial. *Lancet* 2006;368:1239-47 [[17027729](#)]

Eckstein HH, Ringleb P, Allenberg JR, Berger J, Fraedrich G, Hacke W, Hennerici M, Stingele R, Fiehler J, Zeumer H, Jansen O Results of the Stent-Protected Angioplasty versus Carotid Endarterectomy (SPACE) study to treat symptomatic stenoses at 2 years: a multinational, prospective, randomised trial. *Lancet Neurol* 2008;7:893-902 [[18774746](#)]

#### **TESCAS-C (Ling), 2006:**

Ling F, Jiao LQ. Preliminary report of trial of endarterectomy versus stenting for the treatment of carotid atherosclerotic stenosis in China (TESCAS-C).xml HT Chinese Journal of Cerebrovascular Diseases 2006;3(1): 48.\*;

#### **BACASS (Hoffman), 2006:**

Hoffmann A, Taschner C, Engelter ST, Lyrer P, Rem J, Radue EW, et Carotid artery stenting versus carotid endarterectomy. A prospective, randomised trial with long term follow up (BACASS). *Schweizer Archiv fr Neurologie und Psychiatrie* 2006;157:191.

#### **Steinbauer, 2008:**

Steinbauer MG, Pfister K, Greindl M, Schlachetzki F, Borisch I, Schuirer G, Feuerbach S, Kasprzak PM Alert for increased long-term follow-up after carotid artery stenting: results of a prospective, randomized, single-center trial of carotid artery stenting vs carotid endarterectomy. *J Vasc Surg* 2008;48:93-8 [[18486419](#)]  
[10.1016/j.jvs.2008.02.049](#)

#### **ICSS, 2010:**

Carotid artery stenting compared with endarterectomy in patients with symptomatic carotid stenosis (International Carotid Stenting Study): an interim analysis of a randomised controlled trial. *Lancet* 2010 Feb 25;: [[20189239](#)] [10.1016/S0140-6736\(10\)60239-5](#)

#### **CREST, 2010:**

Brott TG, Roubin G, Howard G, et al The Randomized Carotid Revascularization Endarterectomy vs Stenting Trial (CREST): Primary results American Stroke Association International Stroke Conference 2010; February 26, 2010; San Antonio, TX. Abstract 197

Brott TG, Hobson RW 2nd, Howard G, Roubin GS, Clark WM, Brooks W, Mackey A, Hill MD, Leimgruber PP, Sheffet AJ, Howard VJ, Moore WS, Voeks JH, Hopkins LN, Cutlip DE, Cohen DJ, Popma JJ, Ferguson RD, Cohen SN, Blackshear JL, Silver FL, Mohr JP, Lal BK, Mes Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis. *N Engl J Med* 2010 May 26;: [[20505173](#)] [10.1056/NEJMoa0912321](#)

#### **SPACE 2, 0:**

ongoing trial

Reiff T, Stingele R, Eckstein HH, Fraedrich G, Jansen O, Mudra H, Mansmann U, Hacke W, Ringleb P Stent-protected angioplasty in asymptomatic carotid artery stenosis vs. endarterectomy: SPACE2 - a three-arm randomised-controlled clinical trial. Int J Stroke 2009 Aug;4:294-9 [[19689759](#)] [10.1111/j.1747-4949.2009.00290.x](#)

**ACST-2, 0:**

ongoing trial NCT00883402

**ACT I, 0:**

ongoing trial NCT00106938

**Agostoni, 0:**

ongoing trial

**Link, 0:**

ongoing trial