Stent-protected angioplasty in asymptomatic carotid artery stenosis vs. endarterectomy: SPACE2 - a three-arm randomised-controlled clinical trial.

Moderate to severe (> or =70%) asymptomatic stenosis of the extracranial carotid artery leads to an increased rate of stroke of approximately 11% in 5 years. Patients with asymptomatic carotid stenosis, however, are also at a higher risk of nonstroke vascular events. The estimated annual risks of such events in patients with asymptomatic stenosis are 7% for a coronary ischaemic event and 4-7% for overall mortality. The superiority of carotid endarterectomy compared with medical treatment in symptomatic carotid disease is established, provided that the surgical procedure can be performed with a perioperative morbidity and mortality of<6%. The advantage of carotid endarterectomy for asymptomatic patients is less established. An alternative treatment, carotid artery stenting, has been developed. This treatment is used frequently in both symptomatic and asymptomatic patients. In the last decade, major advantages in medical primary prevention of cerebrovascular and cardiovascular disease have been accomplished. The control groups in the large trials for asymptomatic carotid artery disease (ACAS and ACST) originate from more than a decade ago and, for the most part, have not received a medical primary prevention strategy that would now be considered the standard according to
current national and international guidelines. For this reason, a three-arm trial (SPACE2; http://www.space-2.de) with a hierarchical design and a recruitment target of 3640 patients is chosen. Firstly, a superior trial of intervention (carotid artery stenting or carotid endarterectomy) vs. state-of-the-art conservative treatment is designed. In case of superiority of the interventions, a noninferiority end-point will be tested between carotid artery stenting and carotid endarterectomy. This trial is registered at Current Controlled Trials ISRCTN 78592017.