The 2nd European Carotid Surgery Trial (ECST-2)

Principal Investigator:	PD Dr. med. Georg Kägi
Status:	ongoing, recruitment finished
Project Start:	2019
Project End:	unknown
Trial Design/Class:	international, multi-center, randomized, controlled, open, prospective trial /Class B- Other Clinical Trials (ClinO)
Number of Patients:	2000 total,
Centers:	Switzerland (St. Gallen, Bern, Basel, Geneva, Lugano) United Kingdom and other European countries
Sponsor/Partner:	Universitätsspital Basel/University College of London/ PD Dr. med. Leo Bonati
Funding:	Universitätsspital Basel, University College of London

Summary:

Randomised trials have established the benefit of revascularisation by carotid endarterectomy (CEA) for moderate and severe carotid stenosis. However, a risk model derived from one of these trials and validated in another, showed that only patients with a high risk of stroke under medical therapy benefited from CEA. For a large range of patients there was neither clear benefit nor harm from CEA. Medical therapy for stroke prevention has improved since these original trials, with more widespread use of statins, more active lowering of blood pressure and more effective antiplatelet regimes. Lower optimum targets have been set for risk factor control e.g. blood pressure. Therefore CEA may not be beneficial in many patients with carotid stenosis treated by modern optimized medical therapy (OMT).

A risk model based on clinical characteristics to calculate a 5-year Carotid Artery Risk (CAR) score, which will stratify patients as at high risk (≥20%) or lower risk (<20%) of future stroke using predictive data from previous trials recalibrated to take account of the likely benefit of OMT. An interim analysis using MRI to determine the 2-year rates of cerebral infarction and haemorrhage after randomisation will be performed to assess safety and feasibility of the design and inform the design and sample size calculations for the full trial. ECST-2 will incorporate baseline imaging of carotid plaque where possible to investigate the predictive value of plaque characteristics

Objectives

The aim of ECST-2 is to determine the best current regime for treating patients with asymptomatic and symptomatic carotid stenosis who are at lower risk of stroke. Our main hypothesis is that patients who have clinical characteristics that predict a 5-year risk of future ipsilateral stroke of <20% when treated with modern optimized medical treatment (OMT) alone, will not benefit from early revascularisation in addition to OMT, because any reduction in future stroke rates after revascularisation will be balanced by an excess of procedural stroke and death.