International PFO-Consortium

Title: The International PFO-Consortium study

Trial number: NCT00859885

Sponsor investigator, Principal Investigator and
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Status: ongoing, recruitment finished

Summary: The prevalence of patent foramen ovale (PFO) is about 25% in the general population and approximately 40% in patients with ischemic stroke of unknown cause (cryptogenic stroke, CS). Given the large number of asymptomatic patients, no primary prevention is currently recommended. In contrast, patients suffering from a PFO-related ischemic stroke are usually treated with either antiplatelets/ oral anticoagulation (AP/OAC) or percutaneous device closure (PDC). For decades, there was no clear evidence that PDC is superior to medical treatment or vice versa in terms of secondary stroke prevention. Recruitment was completed after including 2000 patients into the study, paralleling the time when several randomized clinical trials pointed to a beneficial effect of PDC compared to AP/OAC in CS patients (age <65y) with a PFO and medium to large right-to-left shunt and/or atrial septal aneurysm for prevention of stroke recurrence. The International PFO-Consortium study is a multicenter registry study comprising 19 hospitals in Europe and the US and represents an alternative data strategy with a large sample size (n=2000) and a 3-yr- follow-up period designed to overcome the difficulties observed in previous clinical trials. The study aims at 1) comparing the risk of recurrent stroke and TIA in CS patients aged ≤ 55 years with PFO who undergo PDC or receive AP/OAC only; 2) assessing the etiological role of PFO for stroke/TIA in patients aged > 55 years; and 3) assessing the risk of recurrent stroke/TIA in “high-risk” PFO patients.