





RASUNOA-prime (Registry of acute Stroke under non-Vitamin K antagonist oral anticoagulants – prime): Objectives and design of a registry-study

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Introduction: Anticoagulation with Vitamin K antagonists (VKA) as well as non-VKA oral anticoagulants (NOAC) is effective in primary and secondary prevention of stroke in patients with atrial fibrillation (AF). Data are lacking on emergency treatment of patients suffering from acute ischemic or hemorrhagic stroke under anticoagulation with VKA or NOAC. The aim of RASUNOA-prime is to describe current patterns of emergency management and outcome of patients with AF experiencing an acute ischemic stroke or intracerebral hemorrhage (ICH) under NOAC or VKA or no anticoagulation.

Method: About 40 certified German stroke units will participate in this observational, multicenter study (ClinicalTrials.gov-NCT02533960). In total 4,000 patients, thereof 3,000 patients with ischemic stroke and 1,000 with ICH, with known AF and patients anticoagulation schemes before stroke (NOAC/VKA/no anticoagulation) will be consecutively enrolled over a period of 3 years. It is ensured that all three treatment arms are equally distributed at any time of recruitment by a standardized enrollment scheme (figure 1). Routine inpatient treatment will be documented in detail. Brain images will be analyzed especially regarding hemorrhagic transformation and hematoma expansion. A three-month-follow up will be performed by a central personal or telephone interview (figure 2).

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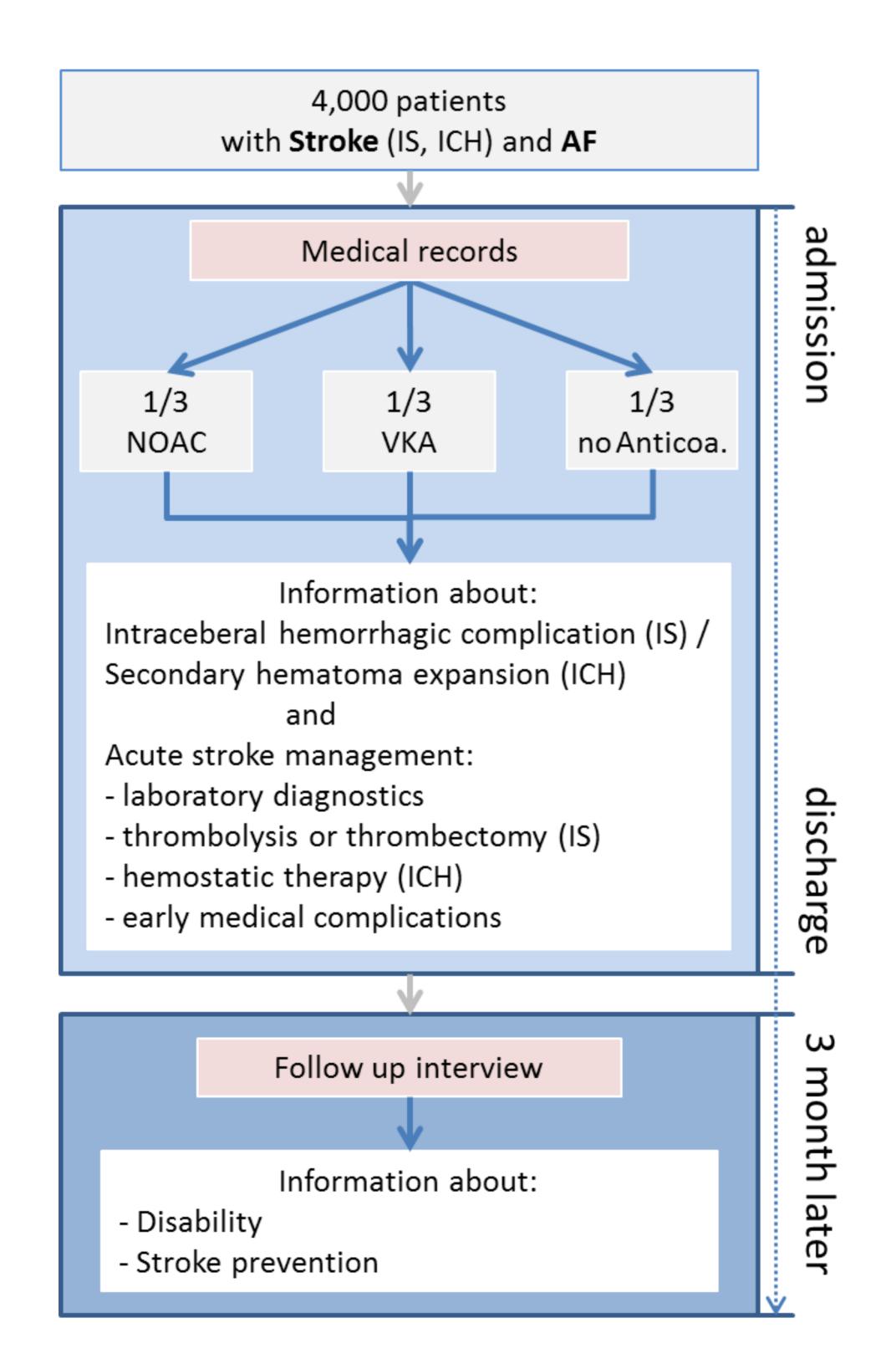


Figure 2: Design and workflow of RASUNOA

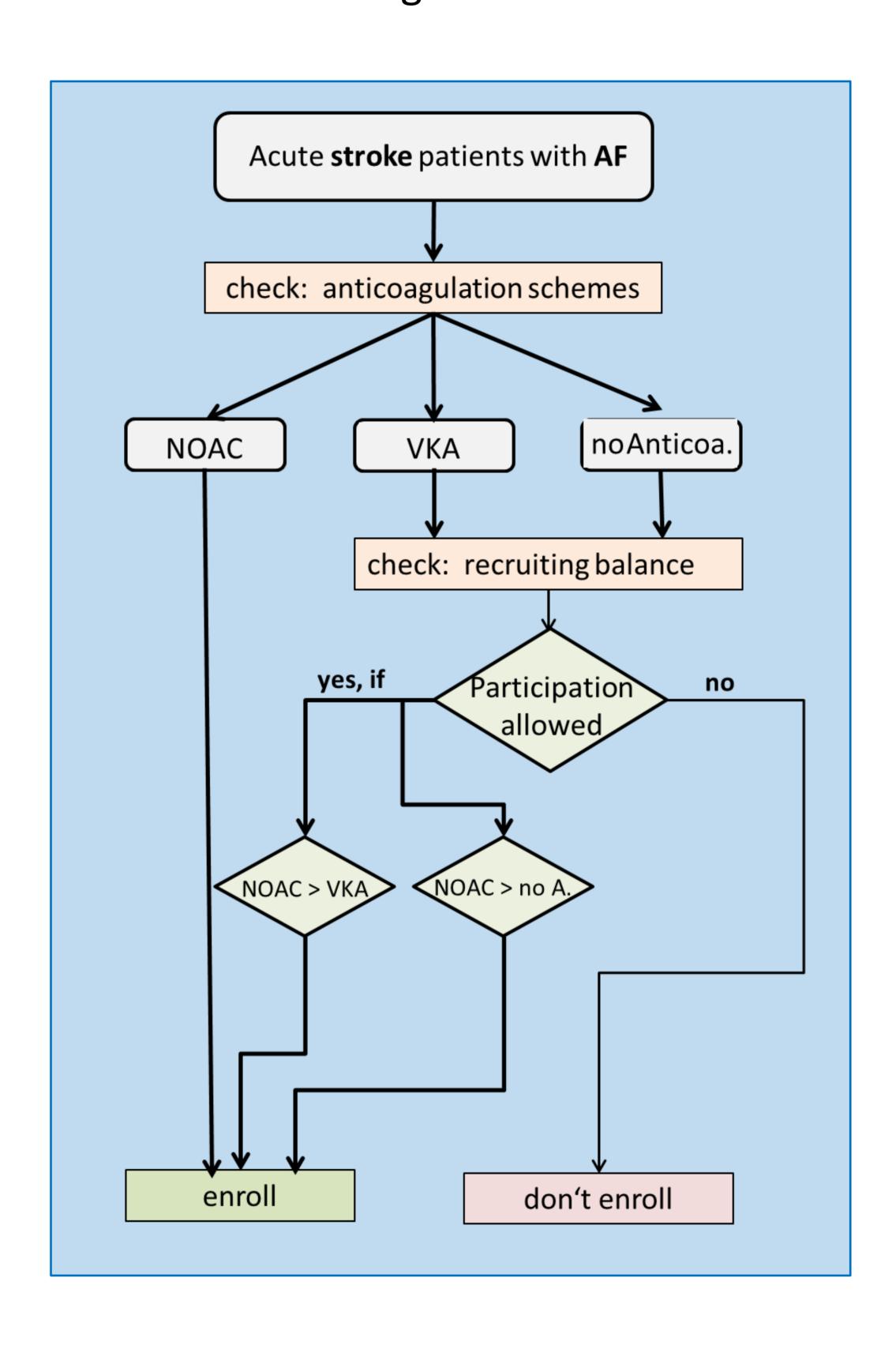


Figure 1: Enrollment algorithm for patient recruitement

Results: The first patient was enrolled in June 2015. As of March 18th, 2016, 32 study centers were initiated and 26 actively recruiting centers included 329 patients. 119 patients enrolled in 2015 were contacted for the three-month-follow up. Information of nearly all patients could be obtained, resulting in a follow up rate of 95 %.

Conclusion: RASUNOA-prime allows a systematic report of emergency management in anticoagulated stroke patients and the evaluation of its short- and long-term outcomes. It will identify factors to inform future interventional trials regarding reperfusion therapies and anticoagulation reversal, respectively.