BACKGROUND: Ischemic stroke is the leading cause of mortality worldwide and a major contributor to neurological disability and dementia. Terutroban is a specific TP receptor antagonist with antithrombotic, antivasoconstrictive, and antiatherosclerotic properties, which may be of interest for the secondary prevention of ischemic stroke. This article describes the rationale and design of the Prevention of cerebrovascular and cardiovascular Events of ischemic origin with terutroban in patients with a history of ischemic stroke or transient ischemic attack (PERFORM) Study, which aims to demonstrate the superiority of the efficacy of terutroban versus aspirin in secondary prevention of cerebrovascular and cardiovascular events. METHODS AND RESULTS: The PERFORM Study is a multicenter, randomized, double-blind, parallel-group study being carried out in 802 centers in 46 countries. The study population includes patients aged >55 years, having suffered an ischemic stroke (<3 months) or a transient ischemic attack (<8 days). Participants are randomly allocated to terutroban (30 mg/day) or aspirin (100 mg/day). The primary efficacy endpoint is a composite of
ischemic stroke (fatal or nonfatal), myocardial infarction (fatal or nonfatal), or other vascular death (excluding hemorrhagic death of any origin). Safety is being evaluated by assessing hemorrhagic events. Follow-up is expected to last for 2-4 years. Assuming a relative risk reduction of 13%, the expected number of primary events is 2,340. To obtain statistical power of 90%, this requires inclusion of at least 18,000 patients in this event-driven trial. The first patient was randomized in February 2006. CONCLUSIONS: The PERFORM Study will explore the benefits and safety of terutroban in secondary cardiovascular prevention after a cerebral ischemic event.