Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Becattini C, Agnelli G, Schenone A, et al. Aspirin for preventing the recurrence of venous throm-boembolism. N Engl J Med 2012;366:1959-67.

Supplementary appendix

Supplement to: Becattini C., Agnelli G., Schenone A., et al. 'Aspirin for prevention of recurrence of venous thromboembolism'.

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Collaborators

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APPENDIX

Exclusion criteria

The main exclusion criteria were known cancer; known major thrombophilia (antiphospholipid antibodies or lupus anticoagulant or homozygous factor V Leiden or prothrombin G21210A or double heterozygosity for factor V Leiden and prothrombin G21210A or deficiency of antithrombin, protein C or S); an indication for long-term anticoagulant therapy other than venous thromboembolism (as atrial fibrillation or prosthetic heart valve); previous symptomatic complications of atherosclerosis requiring treatment with aspirin or other anti-platelet agents; active bleeding or high risk for bleeding or a bleeding episode which occurred during the 6-18 months of anticoagulation; known allergy or intolerance to aspirin; life expectancy shorter than six months; anticipated non-adherence to study medications; pregnancy or breast-feeding; participation in another experimental pharmacotherapeutic program within 30 days before randomization. Women with venous thromboembolism associated with the use of estro-progestin therapy were excluded from the study.

Criteria for diagnosis of recurrent venous thromboembolism

The criteria for the diagnosis of recurrence of pulmonary embolism were a new intraluminal filling defect on computed tomography angiography or pulmonary angiography, or a new high probability perfusion defect on lung scan. In limbs without deep vein thrombosis at baseline, the criteria for the diagnosis of recurrence of deep vein thrombosis was a non-compressible venous segment on ultrasonography or an intraluminal filling defect on venography. In limbs with deep vein thrombosis at baseline, the criteria for the diagnosis of recurrence of deep vein thrombosis were a newly non-compressible venous segment or a substantial increase (4 millimeters or more) in the diameter of the thrombus during full compression on ultrasonography or a new intraluminal filling defect on venography.

Surveillance and follow-up

At each visit, patients were systematically questioned concerning symptoms and signs of recurrent venous thromboembolism, bleeding, and adverse events.

Other anticoagulants and fibrinolytic agents were not allowed during the study period. The administration of non-steroidal anti-inflammatory drugs was allowed with caution if considered necessary.