# 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 thromboembolism. 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'.

**Contents**

**Collaborators**

The members of the WARFASA Study were as follows: **Steering Committee** – G. Agnelli, C. Becattini, P. Prandoni; **Writing Committee** – Cecilia Becattini, M.D., Giancarlo Agnelli, M.D., Paolo Prandoni, Ph.D., Walter Ageno, M.D. Claudio Cimminiello, M.D., Sabine Eichinger, M.D. **Central Independent Adjudication Committee for recurrence of venous thromboembolism and bleeding**: M. Duranti (Chairman), S. Radicchia, F. Guercini; **WARFASA investigators** (at least one patient randomized) – Perugia, Italy - Department of Internal Medicine, University of Perugia: M.C. Vedovati, MD (29); Padua, Italy - Department of Cardiothoracic and Vascular Sciences, University of Padua: D. Tormene, MD, M. Perlati, MD, S. Barbar, MD (32); Genua, Italy - Galliera Hospital, R. Poggio, MD (25); Wien, Austria - Medical University of Wien: L. Leischer, MD (25); Faenza, Italy – Faenza Hospital: E. Bucherini (24); Reggio Emilia, Italy – Arcispedale S Maria Nuova: D. Galimberti, MD, MF. Leone, MD (20); Como, Italy – Valduce Hospital: A. Beretta, MD, A. Carugati, MD (19); Milan, Italy – Angelo Bianchi Bonomi Hemophilia and Thrombosis Center, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico: S. Braham, M.D.(18); Varese, Italy - University of Insubria: E. Romualdi, MD, (17); San Giovanni Rotondo, Italy - Ospedale Sacro Cuore di Gesù: G. Tiscia, D. Colaizzo, M. Grilli, MD (15); Palermo, Italy – Ematologia con trapianto, Dipartimento di Medicina Interna e Specialistica (DIMIS), Azienda Ospedaliera Universitaria Policlinico di Palermo: S. Siragusa, MD (13); Trieste, Italy- Medicina di Urgenza, Ospedale Cattinara: R. Salvi, MD; M. Miccio, MD (12); Gallipoli, Italy – Medicina Interna e Lungodegenza, Ospedale Sacro Cuore di Gesù: L. Ria, MD (12); Vittorio Veneto, Treviso, Italy - Ospedale Civile,: N. Zanatta, MD (12); Florence, Italy – Thrombosis Centre, Department of Heart and Vessels Azienda Ospedaliero-Universitaria Careggi: D. Poli, MD (11); Padua, Italy – Unit of Angiology, University Hospital of Padua: G. Camporese, MD; F. Verlato, MD (11); Ancona, Italy – Medicina di Urgenza, Ospedali Riuniti Umberto I - Lancisi- Salesi: A. Salvi, MD; C. Nitti, MD (11); Alessandria, Italy - Ospedale Civile S Antonio, Biagio e Arrigo: R. Santi, MD (10); Vimercate, Italy - Department of Medicine, Vimercate Hospital, Azienda Ospedaliera di Desio e Vimercate (Monza-Brianza): C. Cimminiello, MD (8); Treviso, Italy - Ospedale Ca' Foncello,: G. Scannapieco, MD (8); Udine, Italy - Ospedale S Maria della Misericordia: G. Barillari, MD, S. Pasca, MD (8); Domodossola, Italy: Ospedale S Biagio: E. De Gaudenzi, MD (7); Siena, Italy: Università di Siena: R. Cappelli, MD (6); Naples, Italy – Regional Reference Centre for Coagulation Disorders, Department of Clinical and Experimental Medicine, Federico II University Hospital: G. Di Minno, MD; A. Tufano, MD (6); Fano, Italy – Ospedale di Fano: G. Frausini, MD (6); Cosenza, Italy - Department of Internal Medicine, Azienda ospedaliera: C. Bova, MD (5);

Monza, Italy - Università Milano Bicocca: E. Pogliani, MD (4); Catania, Italy – Angiologia, Ospedale Garibaldi: S.S. Signorelli, MD (4); Cremona, Italy – Haemostasis and Thrombosis Centre, Istituti Ospedalieri di Cremona: S. Testa, MD, A. Alatri, MD (2); Lamezia Terme, Italy – Internal Medicine: G. Mancuso, MD (2); Florence, Italy – Emergency Department, Azienda Ospedaliero-Universitaria Careggi: S. Grifoni, MD (2); Milan, Italy - Thrombosis Center, IRCCS Istituto Clinico Humanitas: C. Lodigiani, MD (1).

## 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.