



## Outpatient versus inpatient treatment for patients with acute pulmonary embolism: an international, open-label, randomised, non-inferiority trial

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## Résumé en anglais

**Background** Although practice guidelines recommend outpatient care for selected, haemodynamically stable patients with pulmonary embolism, most treatment is presently inpatient based. We aimed to assess non-inferiority of outpatient care compared with inpatient care. **Methods** We undertook an open-label, randomised non-inferiority trial at 19 emergency departments in Switzerland, France, Belgium, and the USA. We randomly assigned patients with acute, symptomatic pulmonary embolism and a low risk of death (pulmonary embolism severity index risk classes I or II) with a computer-generated randomisation sequence (blocks of 2–4) in a 1:1 ratio to initial outpatient (ie, discharged from hospital  $\leq 24$  h after randomisation) or inpatient treatment with subcutaneous enoxaparin ( $\geq 5$  days) followed by oral anticoagulation ( $\geq 90$  days). The primary outcome was symptomatic, recurrent venous thromboembolism within 90 days; safety outcomes included major bleeding within 14 or 90 days and mortality within 90 days. We used a non-inferiority margin of 4% for a difference between inpatient and outpatient groups. We included all enrolled patients in the primary analysis, excluding those lost to follow-up. This trial is registered with ClinicalTrials.gov, number NCT00425542. **Findings** Between February, 2007, and June, 2010, we enrolled 344 eligible patients. In the primary analysis, one (0.6%) of 171 outpatients developed recurrent venous thromboembolism within 90 days compared with none of 168 inpatients (95% upper confidence limit [UCL] 2.7%;  $p=0.011$ ). Only one (0.6%) patient in each treatment group died within 90 days (95% UCL 2.1%;  $p=0.005$ ), and two (1.2%) of 171 outpatients and no inpatients had major bleeding within 14 days (95% UCL 3.6%;  $p=0.031$ ). By 90 days, three (1.8%) outpatients but no inpatients had developed major bleeding (95% UCL 4.5%;  $p=0.086$ ). Mean length of stay was 0.5 days (SD 1.0) for outpatients and 3.9 days (SD 3.1) for inpatients. **Interpretation** In selected low-risk patients with pulmonary embolism, outpatient care can safely and effectively be used in place of inpatient care. **Funding** Swiss National Science Foundation, Programme Hospitalier de Recherche Clinique, and the US National Heart, Lung, and Blood Institute. Sanofi-Aventis provided free drug supply in the participating European centres.

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