Reviewer's report

Title: Incident venous thrombotic events in the Prospective Study of Pravastatin in the Elderly at Risk (PROSPER).

Version: 1 Date: 11 July 2010

Reviewer: Sigrid K Brækkan

Reviewer's report:

The current study has investigated the impact of pravastatin on prevention of venous thromboembolism (VTE) in the elderly, and adds new information to our knowledge on the role of statins in VTE prevention. The paper is well written.

Major comments

1. My major concern is the outcome assessment and classification. A definite VTE should be objectively confirmed by radiological procedures. A record of anticoagulant treatment for three months is not sufficient to confirm a diagnosis of VTE, and thereby classify an event as definite. Preferably, a more restrictive classification of definite VTE should be used.

2. In the present paper, almost 20% of the total cases were classified as probable cases (a number that would be even higher if definite cases were restricted to those objectively confirmed). The authors state in the discussion section, last paragraph, that analysis using definite VTE only, yielded similar results to those using the total VTE cases. Hazard ratios with 95% CI for definite VTE by pravastatin vs. placebo should also be provided in the results section.

3. The prospective nature of PROSPER do not allow adjustments for transient or precipitating risk factors due to lack of information on factors other than cancer in the whole study population. However, it would be intriguing to know whether cases were unprovoked or provoked, and whether there was any imbalance in the proportion of unprovoked/provoked VTEs between the treatment and placebo groups. Information on transient or precipitating risk factors among the cases, as well as information on the proportion of incident and recurrent VTE, would be preferable.

4. The dosage of pravastatin used in the trial should be provided in the text.

Minor comments

1. A table presenting the baseline characteristics of each treatment group would be helpful for the reader.

2. Results section, second paragraph, second line: The word “with” is missing
Discussion section, second paragraph, sixth line: The word “greater” is superfluous
**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.