Reviewer's report

**Title:** SUrgical versus PERcutaneous Bypass: SUPERB-trial; Heparin-bonded endoluminal versus surgical femoro-popliteal bypass; a multicentre randomized controlled trial: design and rationale

**Version:** 2 **Date:** 28 June 2011

**Reviewer:** David Kent

**Reviewer's report:**

Overall, this is a straightforward randomized trial comparing surgical to endovascular fem-pop bypass. I have only relatively minor comments, which are nevertheless compulsory to address.

1. The wording for the power calculation was unclear: "The power analysis was based on a non-inferiority principle, with an effect size of 90% and 10% margins (alpha 5%, power 80%)." Effect size usually refers to the difference between the control and treatment group. Does 90% refer to the estimated patency rate at one year in the control (surgical) arm? Please clarify the protocol.

2. This study has two primary aims. One is a non-inferiority aim. The other is a superiority aim. The statistical analysis should show power calculations for both primary study aims.

3. The subgroup analysis is a bit unclear. Usually, subgroup analyses are conducted to explore the possibility of heterogeneity of treatment effect (i.e. differences in the treatment effect across subgroups). In this case, the subgroup analysis refers to analyzing a different outcome only within a subset of patients. A non-inferiority trial analyzed only on a subsample of patients is very likely to show non-inferiority in that subset, if only due to lack of power. The authors should estimate the power for this subset analysis, or (probably more appropriate) clearly label these analyses as exploratory (hypothesis generating, not hypothesis testing).

In addition to the above comments, the authors should carefully review the writing, as there are grammatical issues that degrade the clarity of the writing in several sections. Also, please make sure that all the abbreviations are fully spelled out at first use (e.g. TLR (in abstract), PSV, etc.).