Reviewer's report

**Title:** Dutch randomized trial comparing standard catheter-directed thrombolysis versus Ultrasound-accelerated Thrombolysis for thromboembolic infrainguinal disease (DUET): design and rationale [ISRCTN72676102]

**Version:** 4 **Date:** 13 October 2010

**Reviewer:** Roger Malcolm Greenhalgh

**Reviewer's report:**

The paper is well written and well laid out and I note the background review. It is useful that a recent systematic review is quoted.

The authors are wrestling with the possibility that ultrasound accelerated thrombolysis takes less time to act on thrombus than normal thrombolysis. I find this a worthy hypothesis. The primary endpoint is the time of catheter directed thrombolysis required. I would note that the crural arteries may cause significantly more difficulty and it should be important that equal numbers are allocated to each group. A stratification is advised. I note the various secondary endpoints and the patients to be included.

Under eligibility criteria it becomes very plain that a mixture of thrombosed femoropopliteal or femorocrural bypass grafts will be used and also some will be vein and some prosthetic. It should be noted that prosthetic bypass to crural vessels is especially susceptible to primary thrombosis and also secondary thrombosis. Thus stratification for this is also to be considered. The numbers in the groups may not be large enough (30 v 30) to do this adequately and statistical advice is vital. I note the list of adverse events and the groups.

In summary it is a worthwhile topic to pursue and expertise outside my own will need to comment on the issues raised here.

1. I believe the study design tests the hypothesis potentially (if numbers are adequate).
2. Replication of the work should be possible after this trial.
3. Expert statistical input is required particularly on the issues raised above.
4. The writing and layout is excellent.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:

No competing interests